Chapter

3

ProFoRMS

CHAPTER 3 - PROFORMS

The **Protocol** and **Form Research Management System (ProFoRMS)** module provides the tools for protocol management, data capture, and is a clinical trial/research module. ProFoRMS is a web-based data collection/research application organized by modules, with a user-friendly interface designed to help researchers to manage individual studies, subjects, eCRFs (electronic Case Report Forms), data collection, define electronic case report forms, schedule, and collect clinical data, and then export, analyze, and report on the data. This module is based on NICHD's Clinical Trail Database (CTDB).

WARNING!

ICON KEY

Notes

Important Information

Things to Note:

Before a protocol can be created, please make sure that the following has been completed:

- A study has been created and approved in the Data Repository;
- e-Form(s) has been published in the Data Dictionary; and
- Proper permissions are granted to the e-Forms (if the eform is not standardized) for users who are collecting data against the form.

3.1 Objective

This chapter provides information for users on how to:

- Manage Protocol
- Manage Subjects
- Collect Data
- Reports and Data Query

3.2 System Functions

The main function of ProFoRMS is to provide the tools that help to optimize the clinical study process including the basic functions of managing protocols, subjects as well as data access and acount management. Early deployment of ProFoRMS in the study start-up activities, such as site identification, initiation of subject visits, and collection of all the necessary regulatory documents, can save researchers' time and improve the overall process.

As a web-based database application, BRICS provides real-time tools that support:

- Data Contribution
- Report and Query Data
- Collect Data

Once a study is running, ProFoRMS can assist users to keep track of subject visits, data collection and of all the relevant forms and regulatory documents. This provides a strong snapshot of progress in terms of study progress and site activation. The ability to track this information ensures that any potential delays can be identified quickly and addressed.

3.3 ProFORMS Roles and Privileges

The table below describes the specific roles with associated privileges to ProFoRMS module.

Role/Access	Privilege
Global Administrator Access	Create, design, and administer forms for prospective collection
Non-Admin Access	Users with this role can view forms and collect data
All Privileges	Create, design, and administer forms for prospective collection
Associate Investigator	Same as PI, except AI cannot add/initiate a study.
Clinical Research Associate	Can view anything but not allowed to change except adding QA Monitor query
Data Entry	Users with this role can view forms and collect data
Data Entry Users	This Role includes: - Viewing: Protocol/Study, Visit Types, Data entry, Forms, and Attachments – Editing/managing scheduled visits – Data entry/editing/viewing e-forms – Viewing response data.
Principal Investigator	Create, design, and administer forms for prospective collection

3.4 USING PROFORMS

The **ProFoRMS** module (including sub-modules) are available within the BRICS Workspace.

ICON KEY

Notes

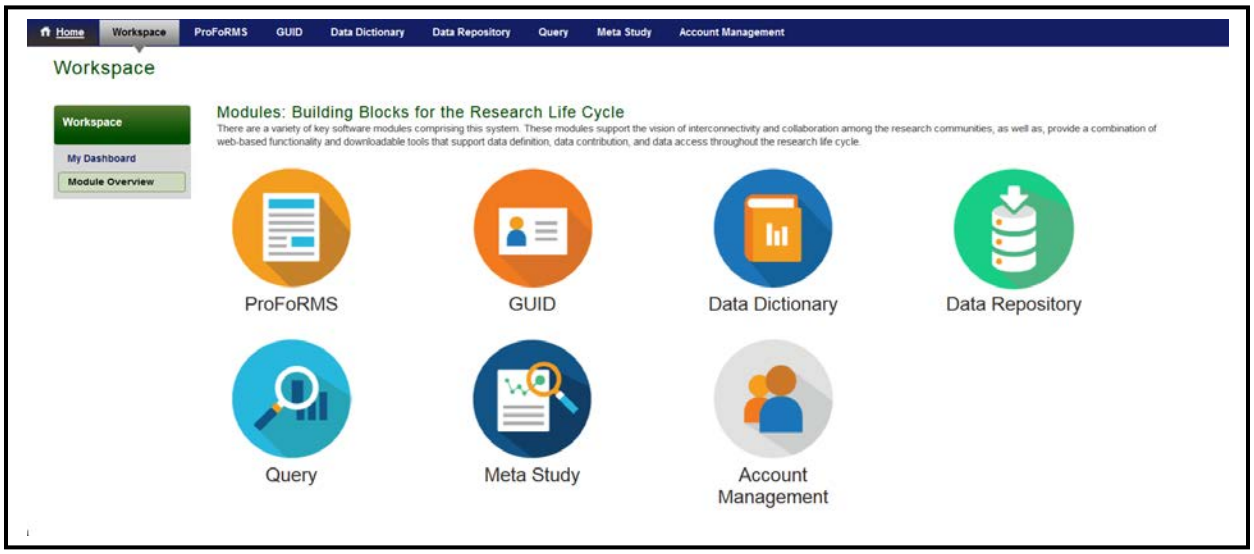
Important Information

Things to Note:

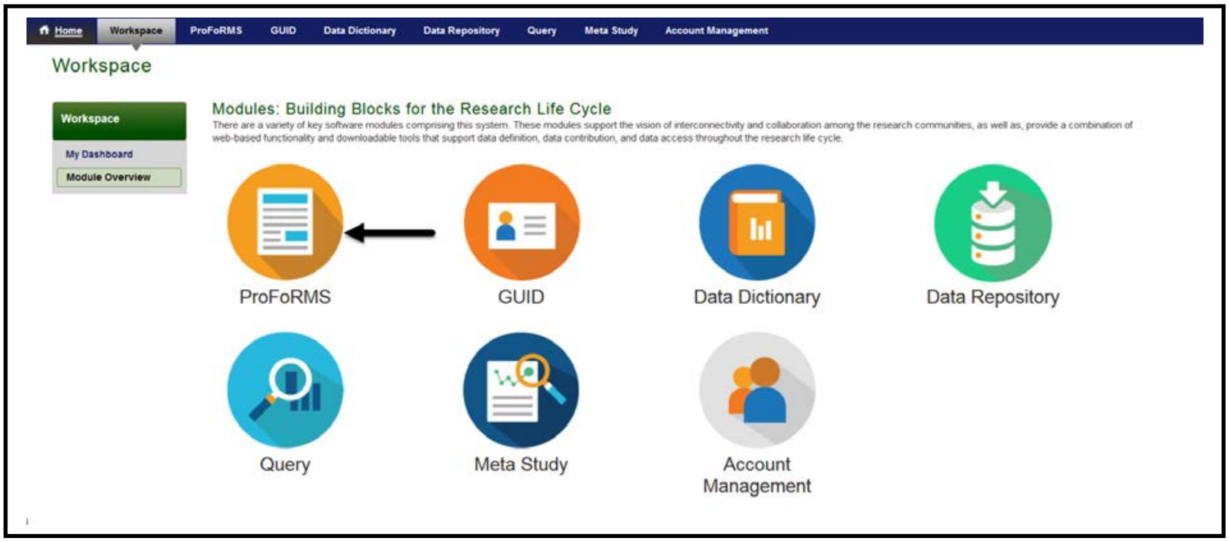
- The best user experience with navigating through the ProFoRMS module is with the latest Firefox browser
- Java Runtime Environment (JRE) version 8 or higher is required. Check your version of Java.

To access the ProFoRMS module**:** Perform the following actions:

1. Login and navigate to the **Workspace screen** where all modules you have access to are displayed.



2. Click the **ProFoRMS** module to enter ProFoRMS.



WARNING!

ICON KEY

Notes

Important Information

Things to Note:

A Protocol must be created first before users can navigate to My Subjects and start adding subjects or managing and/or editing subjects. Refer to section 3.5.2 of this document instruction on creating a protocol.

3.5 My Subjects

This feature is designed to help the researchers to add and edit subject information, schedule subject visits, track individual subjects across multiple studies within the system, upload subject related document, etc.

The **My Subjects** page lists all subjects currently enrolled into the protocol. The user can sort the list of subjects by **Subject ID**, **First** and **Last Name**, **Status**, **Group**, **Validation Status**, **Study Number**, and the **Monitor Query** status. The table also has a simple search box.

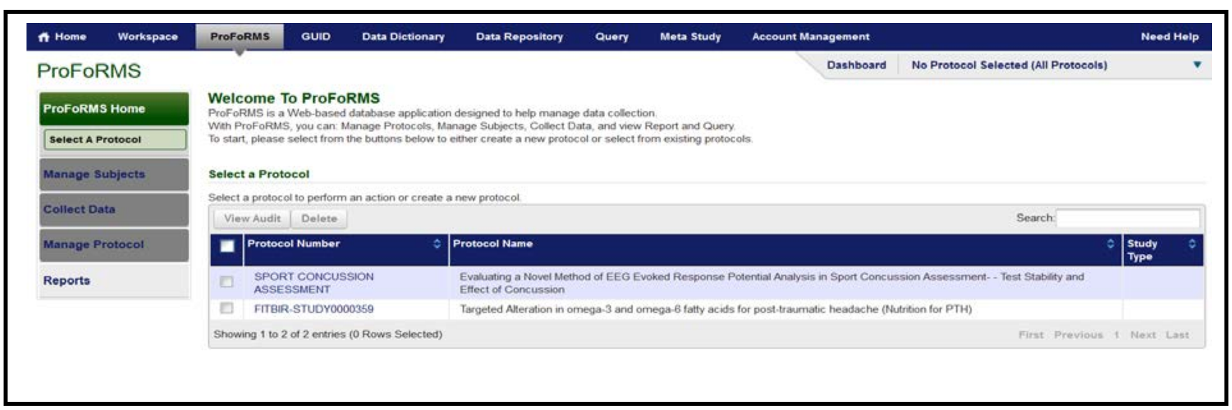
The menu options allows the user:

- ❖ To view and edit subject's information;
- ❖ To view and upload subject related documents;
- ❖ To view forms completed for a selected subject;
- ❖ To view the audit information;
- ❖ To add the monitor query;
- ❖ To schedule a visit;
- ❖ To delete selected subjects; and
- ❖ To search for a subject using a keyword.

3.5.1 Access My Subject

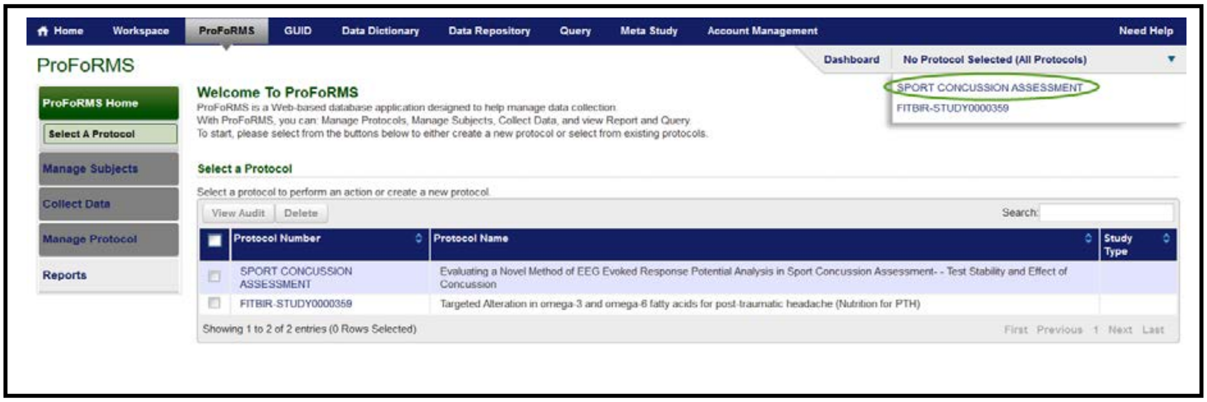
To access My Subjects page**:** Perform the following actions:

1. Login to the system.
2. Navigate to the **ProFoRMS** module

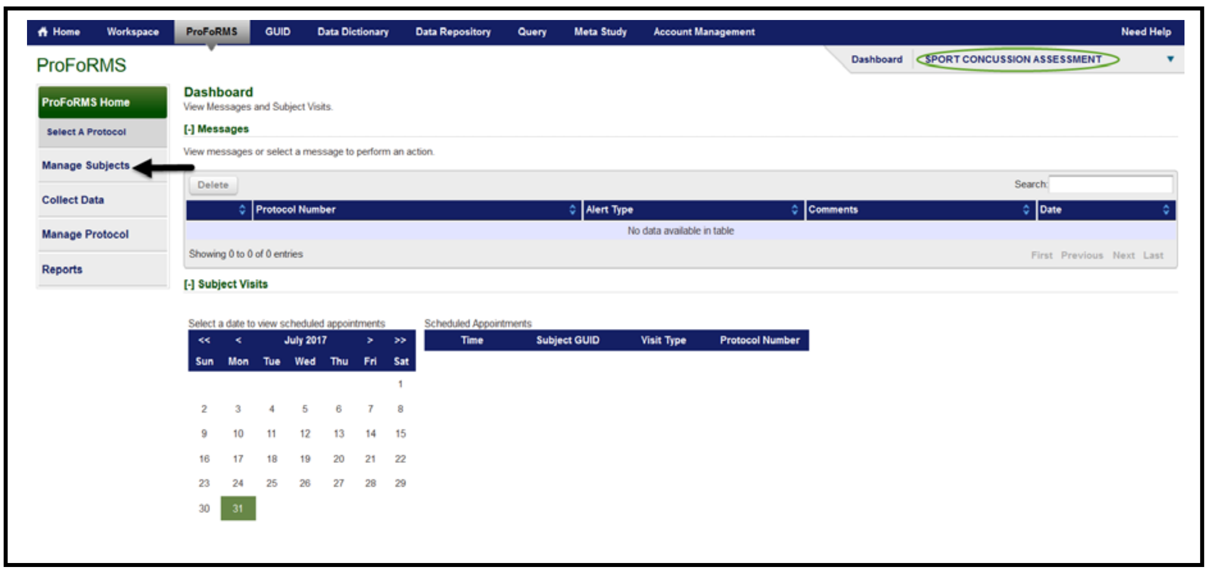


3. Select a **Protocol** by using the drop-down menu located on the top right-hand corner.

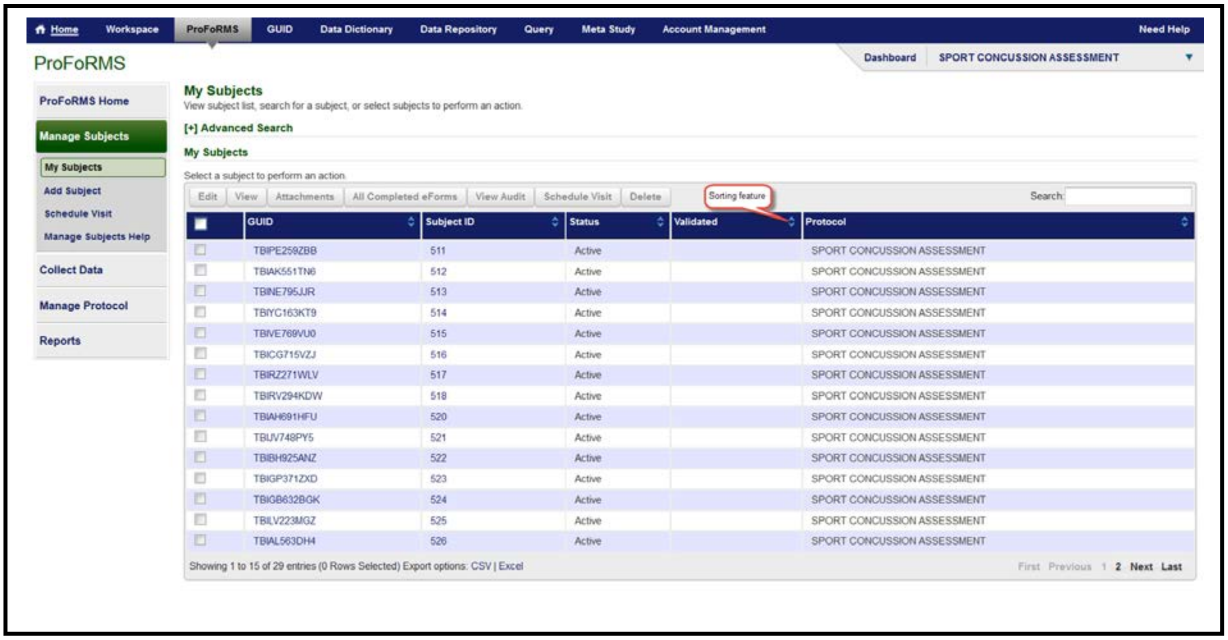
   Note: Many of the features on the left-hand side will not be active until a protocol is selected. If you are unable to select a protocol from the drop-down menu, please contact the **Operations Team** for assistance.



4. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



5. **My Subjects** page appears with a list that can be sorted by clicking on the arrows on any field using the symbol. While in the Subject view, you may *View Subject lists*, *Search for Subject* or *Select Subjects* to perform any desired action.



Things to Note:

🗁 The **My Subjects** toolbar is available when the user selects a subject from the list.

ICON KEY

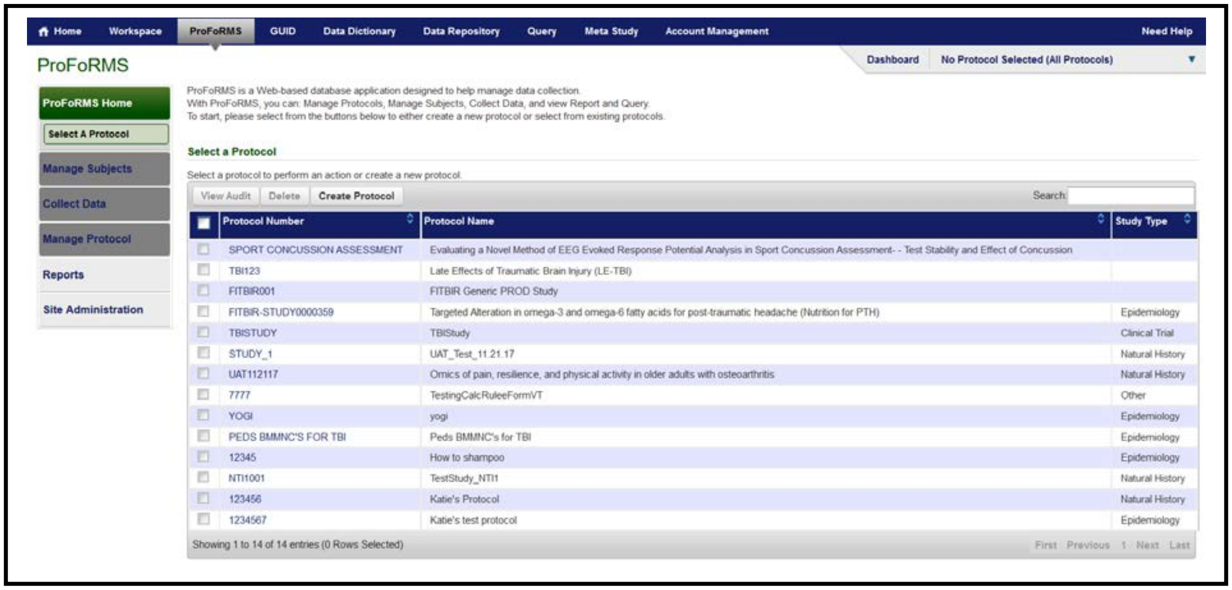
🕮 Notes

🗁 Important Information

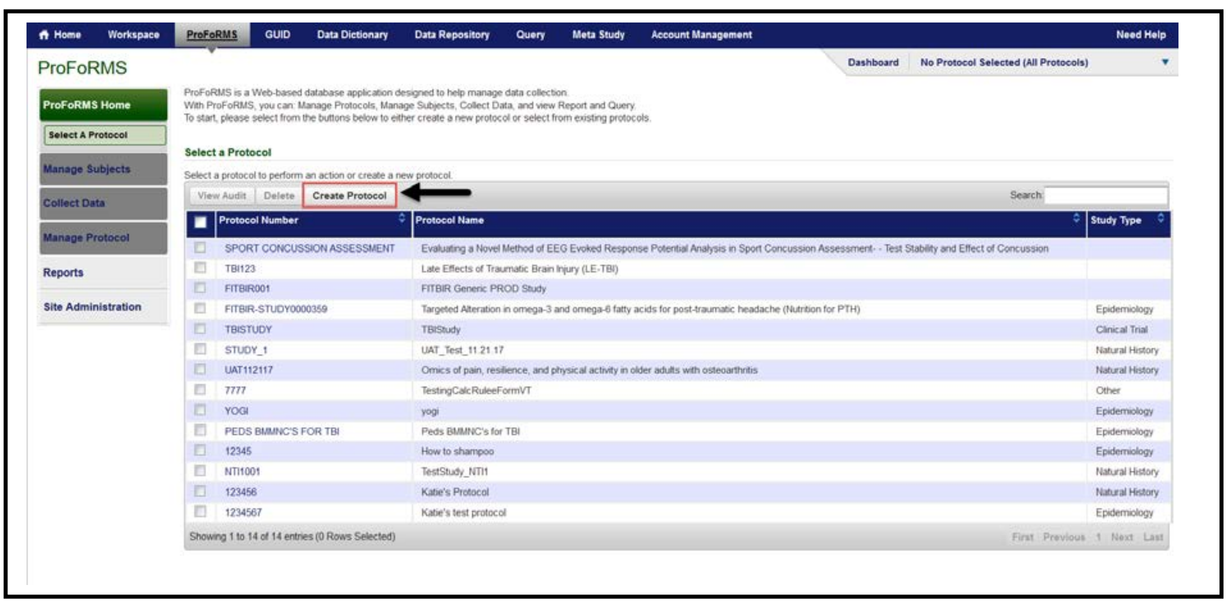
3.5.2 Create a Protocol (Select a Protocol if already created)

To create a Protocol: Perform the following actions:

1. Navigate to the **ProFoRMS** home page.

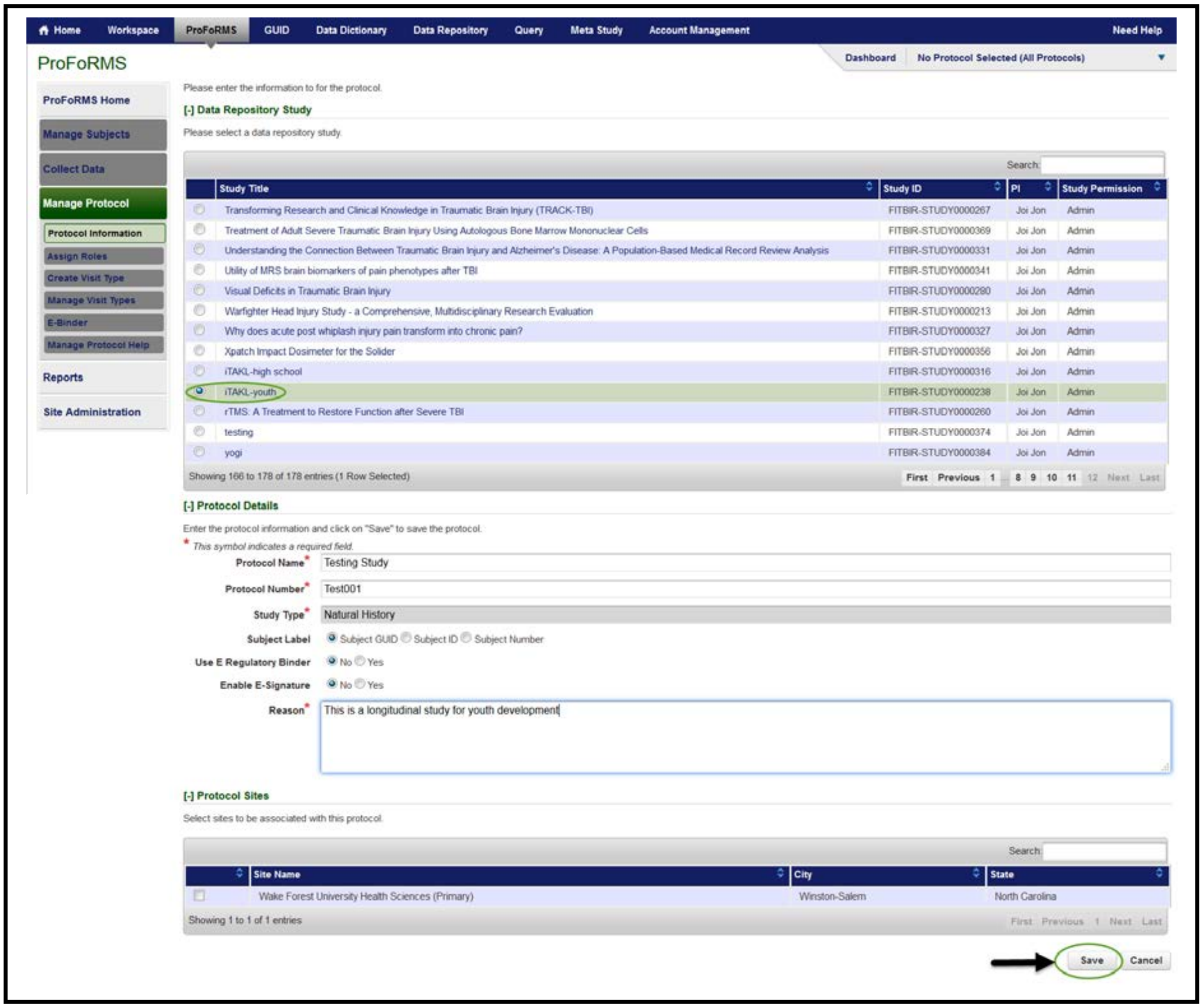


2. Click the **Create Protocol** button**.**



4. *Type, Reason etc.*.) (all required fields (the ones marked with a red asterisk (*)).). Remember to select the **Protocol Site(s)** to be associated with your protocol

   Before saving a protocol, you must also select a study in the Data Repository (doing this will automatically populate the Study Type required field information). Click the **Save** button. The new protocol will appear in the protocol list under My Protocols.



3.5.3 Selecting a Protocol

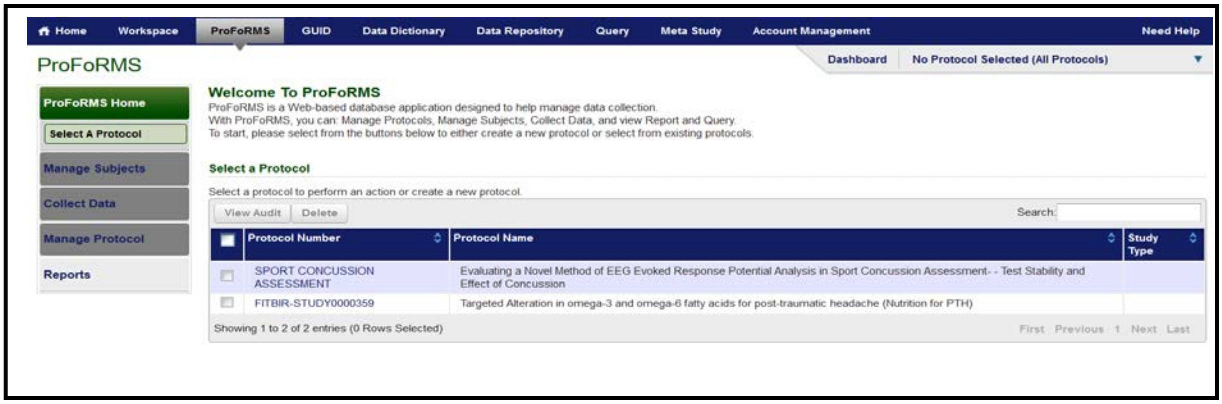
The viewing and selecting a protocol can be done in ProFoRMS via two ways:

- ❖ Using the pick a protocol drop-down list; and
- ❖ Using the Select a Protocol left-hand menu

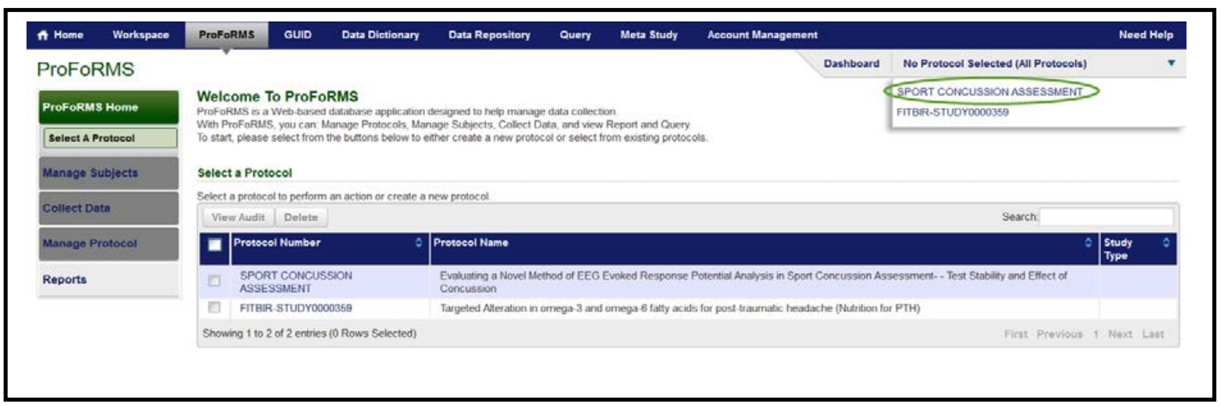
Using the Drop-down List

To select a Protocol in ProFoRMS using the drop-down list: Perform the following actions:

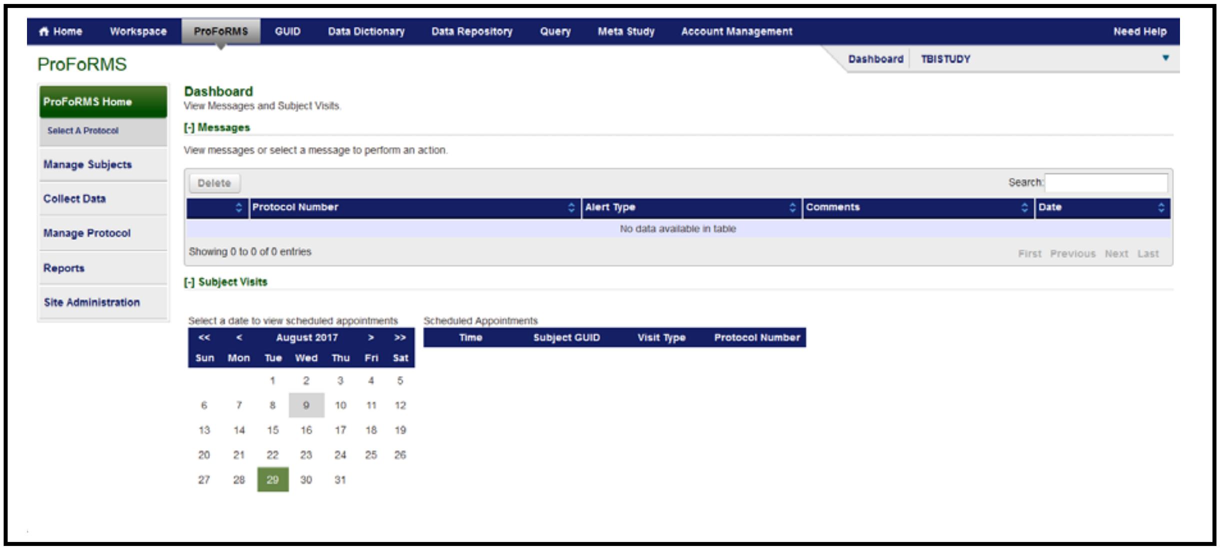
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand. The list of available protocols appears.



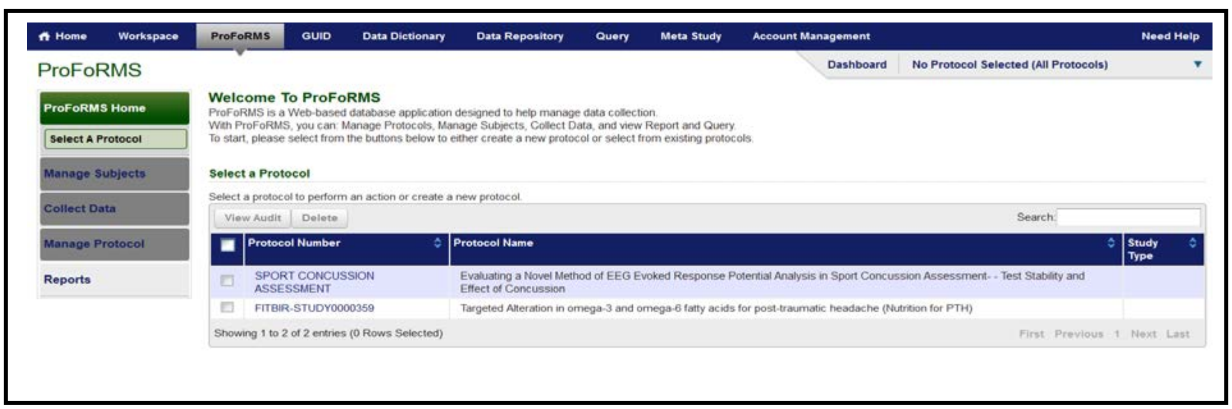
3. Click on the desired Protocol. The system will load the selected protocol data including the list of subject visits and messages.



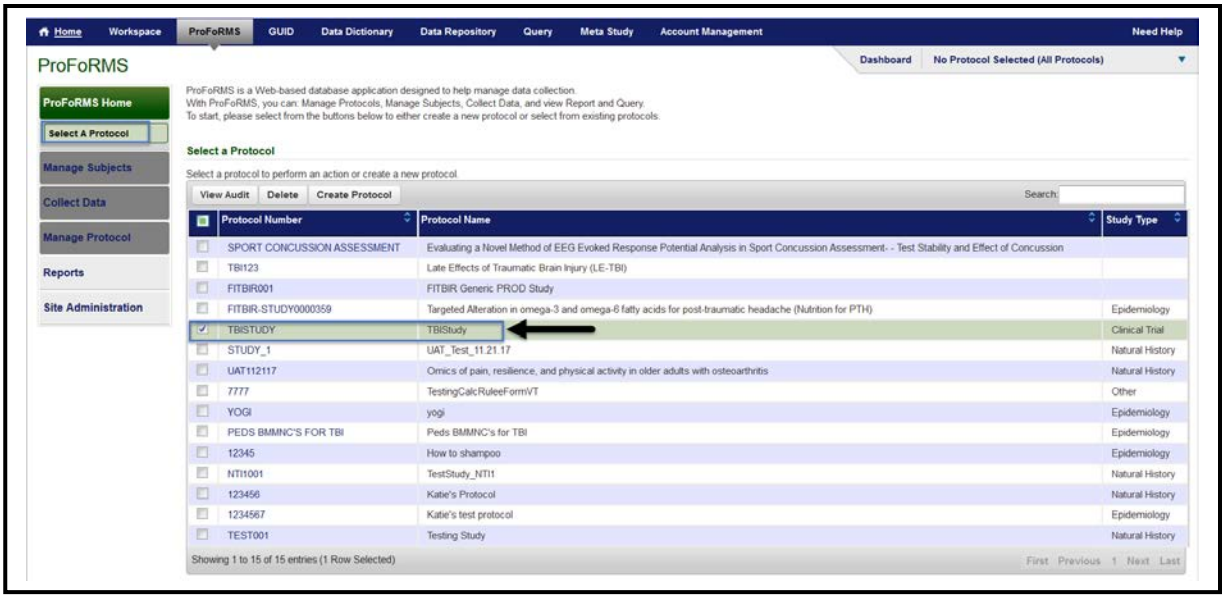
Using the Select a Protocol button:

To select a Protocol in ProFoRMS using the protocol button: Perform the following actions:

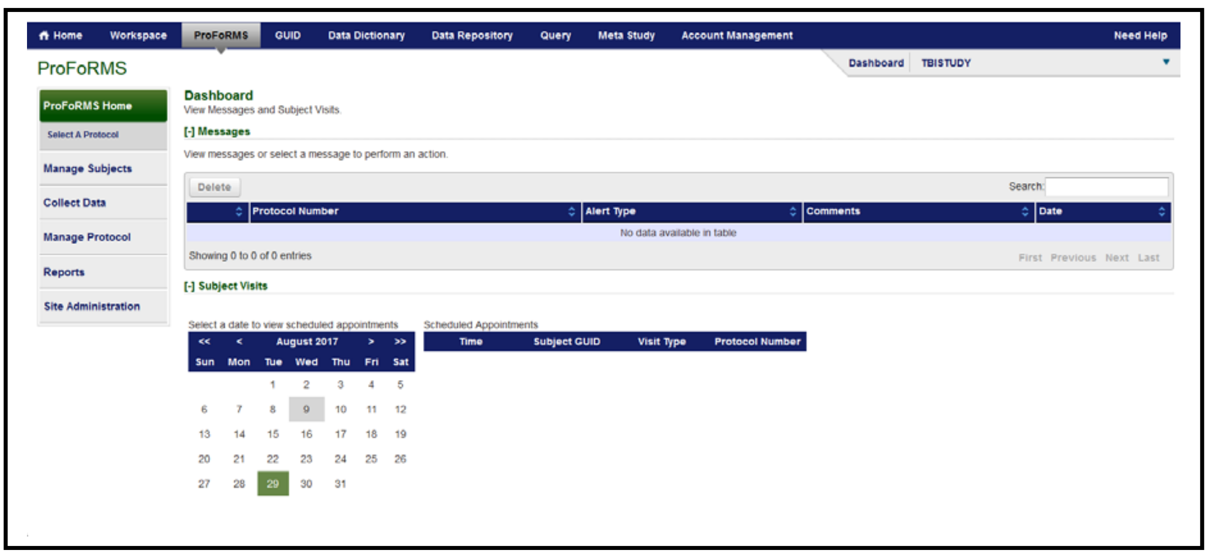
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by clicking on the **Select A Protocol** button on the left-hand. The list of protocols appears. Select a protocol by clicking on the desired protocol number.

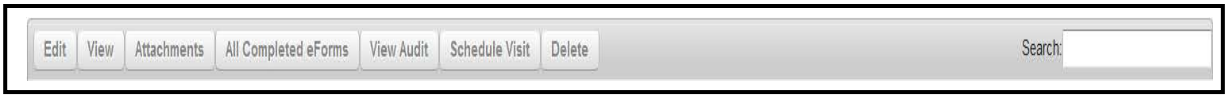


3. The system will load the selected protocol data including the list of subject visits and messages.



3.6 MANAGE SUBJECTS

This feature is designed to help you **Edit, View, View All Completed eForms, Schedule Subject Visits and Delete Subjects** and track individual subjects across multiple studies within the system, and upload subject-related documents.

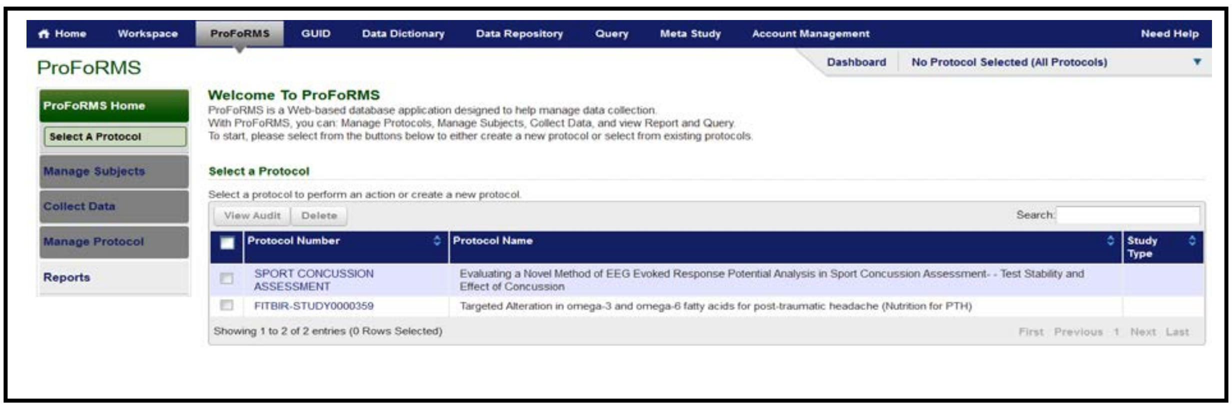


3.6.1 Add Subject

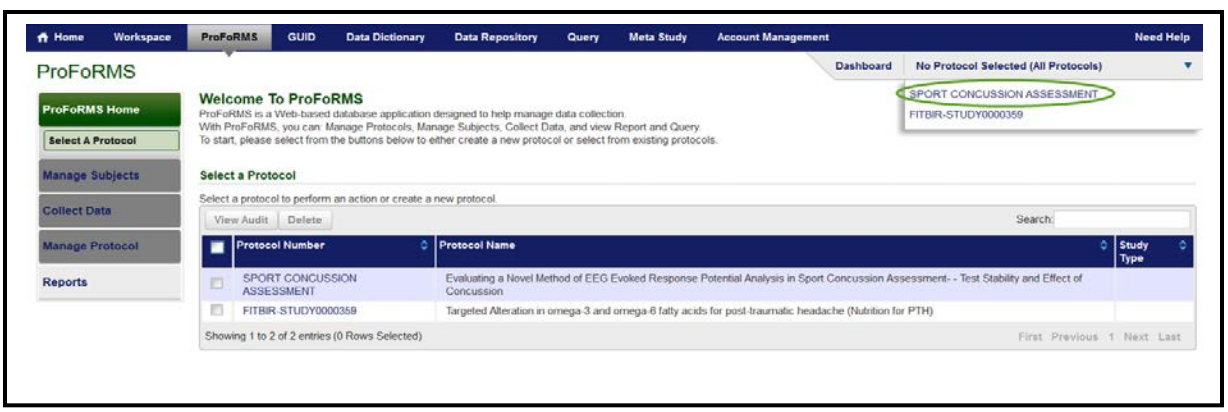
To add a subject (a research participant) to a Protocol, the subject must be provided with a unique Identification number (ID). The goal is to provide the identification number, which allows the researchers to associate data with the subject without exposing or transferring the subject's Personally Identifiable Information (PII). This is done by using the Global Unique Identifier (GUID). For more information about the GUID, please refer to **Chapter 6 GUID.**

To Add Subject: Perform the following actions:

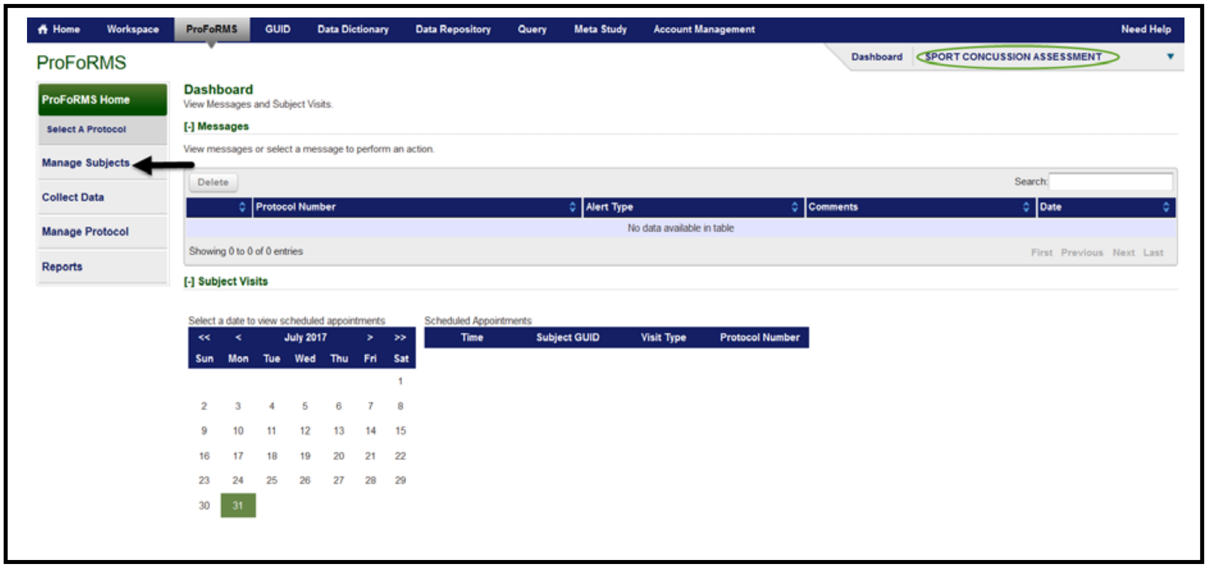
1. Navigate to the **ProFoRMS** module



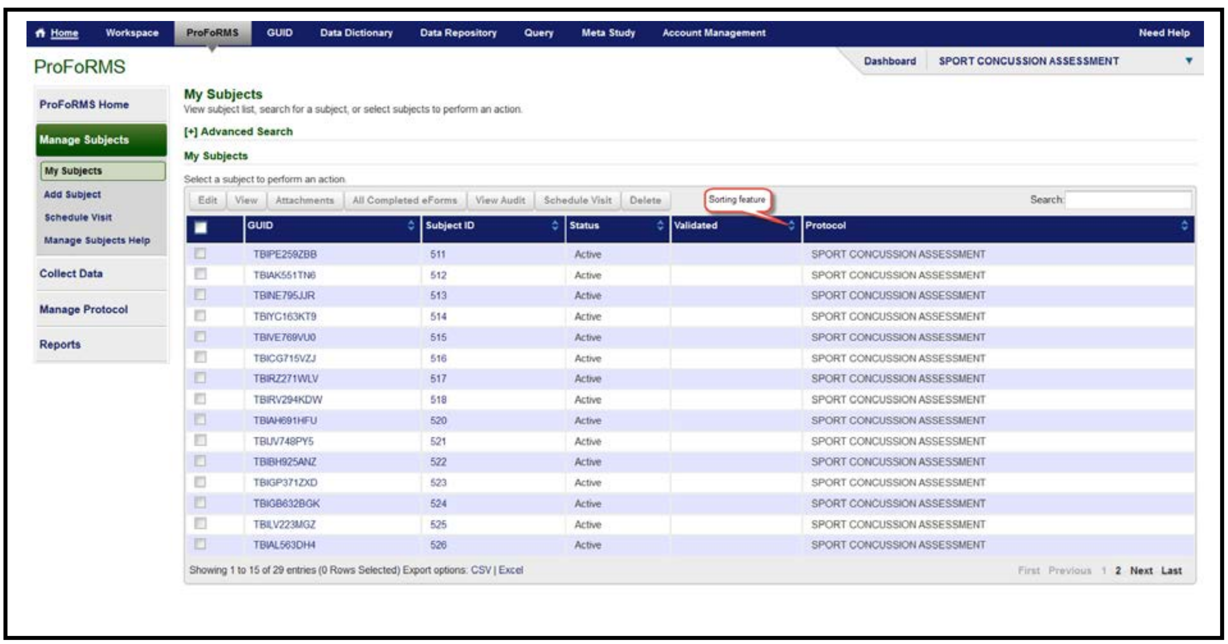
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



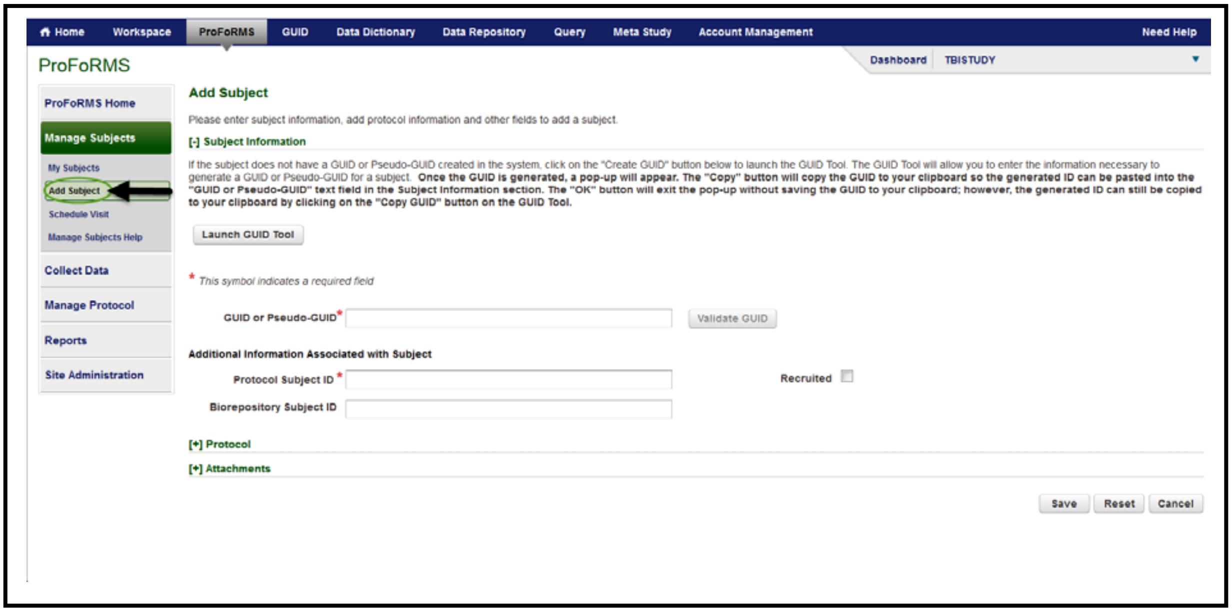
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



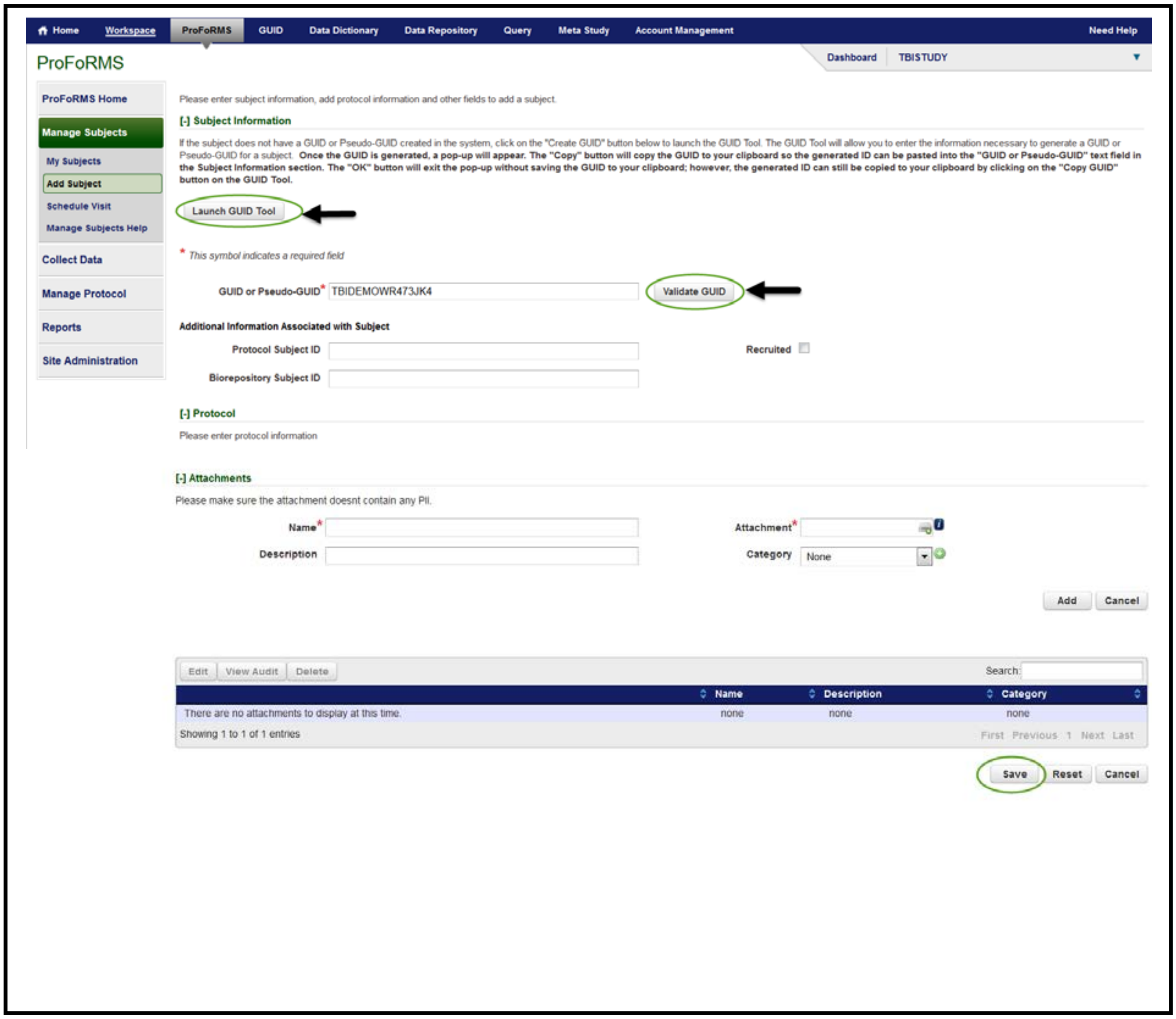
4. **My Subjects** page appears with in a list that can be sorted by clicking on the arrows on any field using the symbol.



5. Click the **Add Subject** tab on the left-side tool bar.

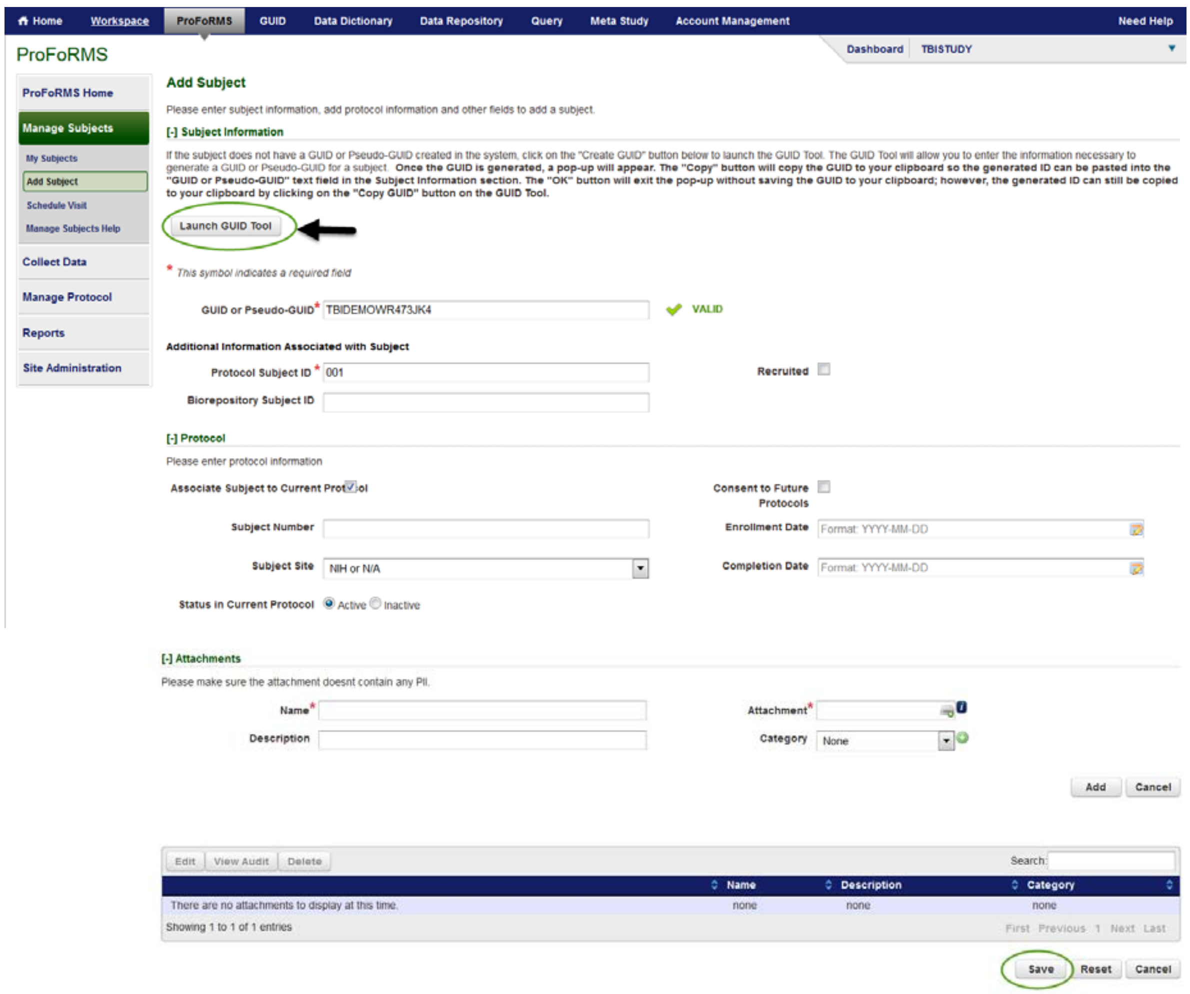


6. Enter the required **Subject Information** to add a subject. **(Note:** Study Subject ID is unique across the system. Sites entering this information must use a prefix (i.e. UTSW_001, JHU_001))using the [-] feature). Expand the form to Enter the **Study Information** and attach any relevant documents as required. Making sure the attachment doesn't contain any PII. Type in the GUID and click **the Validate GUID** button to validate the GUID for the current subject. After entering all the required protocol information, click the **Save** button.



7. If the subject does not have a **GUID** or **Pseudo-GUID** created in the system, Click on the "**Create GUID**" button below to launch the GUID Tool. ([See section 3.7.2 for instruction on launching the GUID tool](#)). Mandatory fields are marked with asterisk *. Once all the mandatory fields are complete, click the **Save** button.

   Click the **Save** button to return to **My Subject** screen where the newly added Subject can be viewed.

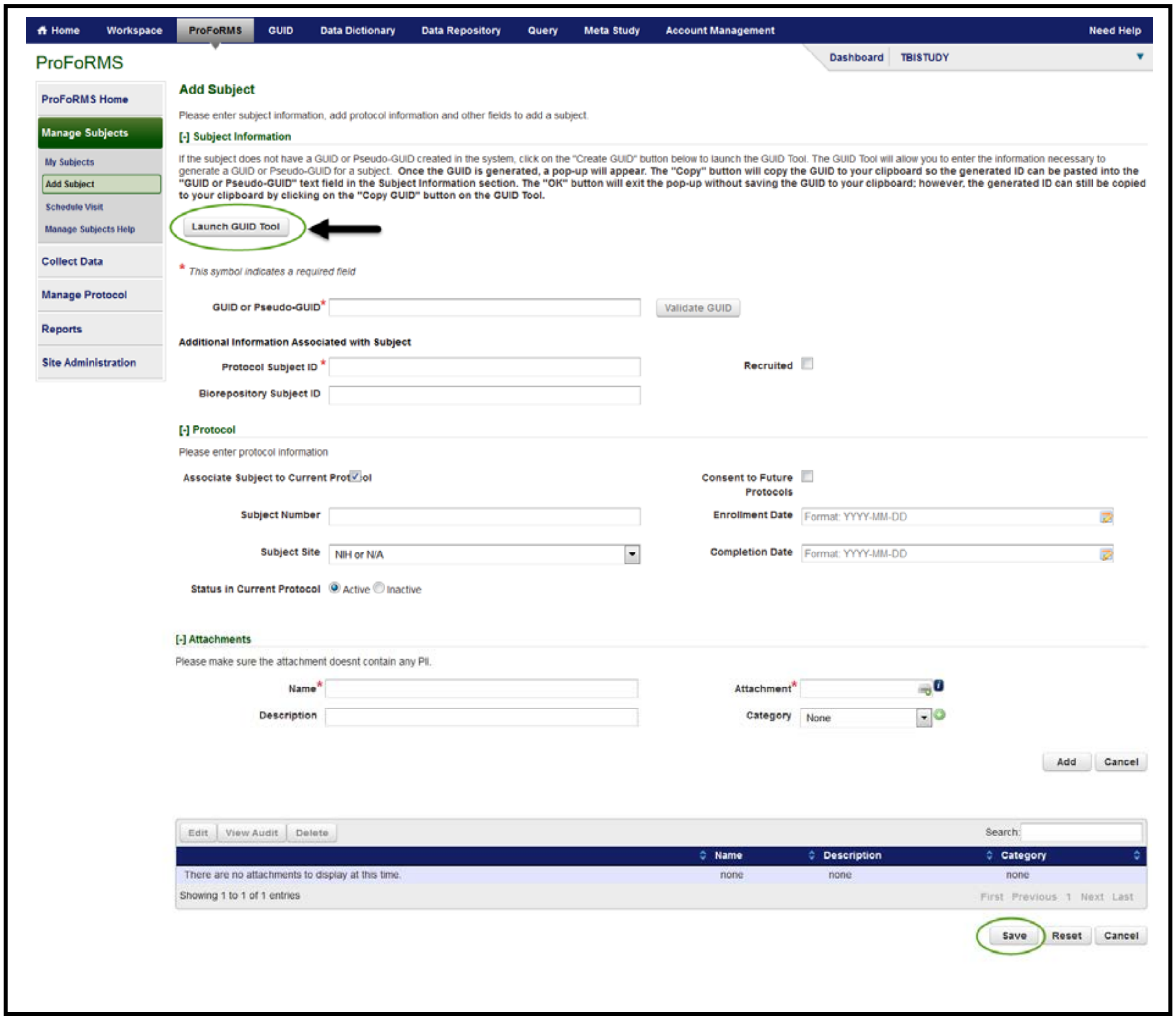


3.6.2 Launching the GUID Tool

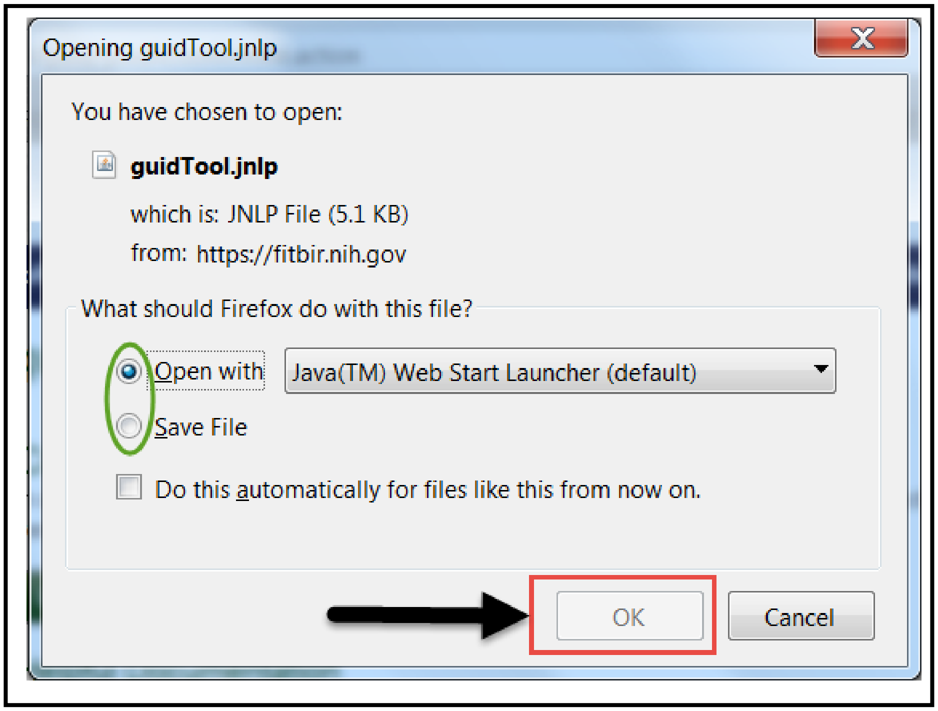
From the **Add Subject** page, you can launch the GUID Tool. **NOTE**: Only Users with correct permissions/access to the GUID module are able to launch the GUID Tool.

To Launch the GUID Tool: Perform the following actions:

1. Click on the **"Launch GUID Tool"** button below to launch the GUID Tool. The GUID Tool will allow you to enter the information necessary to generate a GUID or Pseudo-GUID for a subject. Once the GUID is generated, a pop-up will appear. The **"Copy"** button will copy the GUID to your clipboard so the generated ID can be pasted into the "GUID or Pseudo-GUID" text field in the Subject Information section. The **"OK"** button will exit the pop-up without saving the GUID to your clipboard; however, the generated ID can still be copied to your clipboard by clicking on the **"Copy GUID"** button on the GUID Tool.

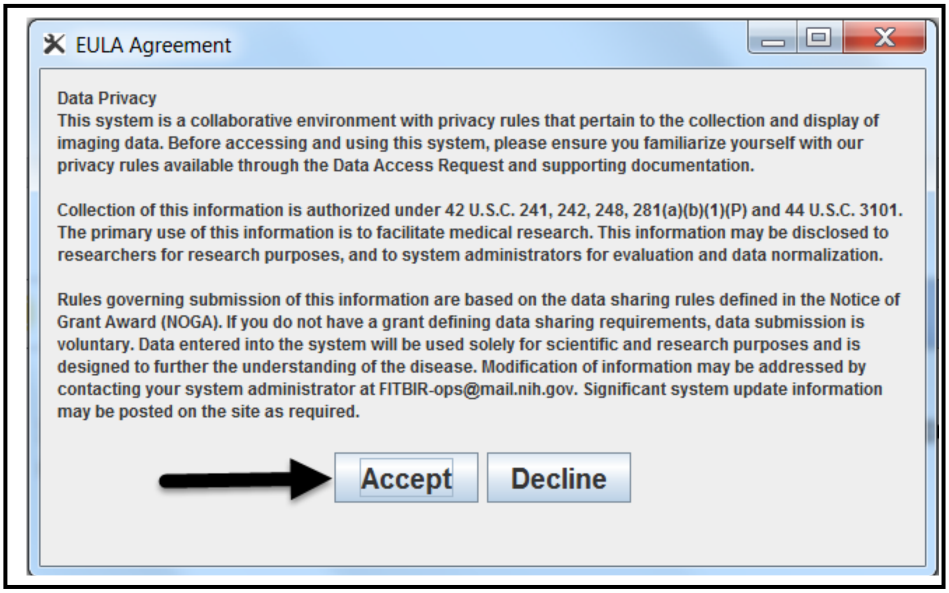


2. In the Opening **guidTool.jnlp** window that appears, Click **Open with Java(TM) Web Start Launcher** (default) and Click **OK**.



3. In the **Java Runtime Environment** (JRE) window that appears next saying "**Do you want to run this application**?", Click **Run.**

4. The EULA Agreement window appears displaying the data privacy user agreement. Read the agreement and Click **Accept** if you agree. The GUID Client window appears.



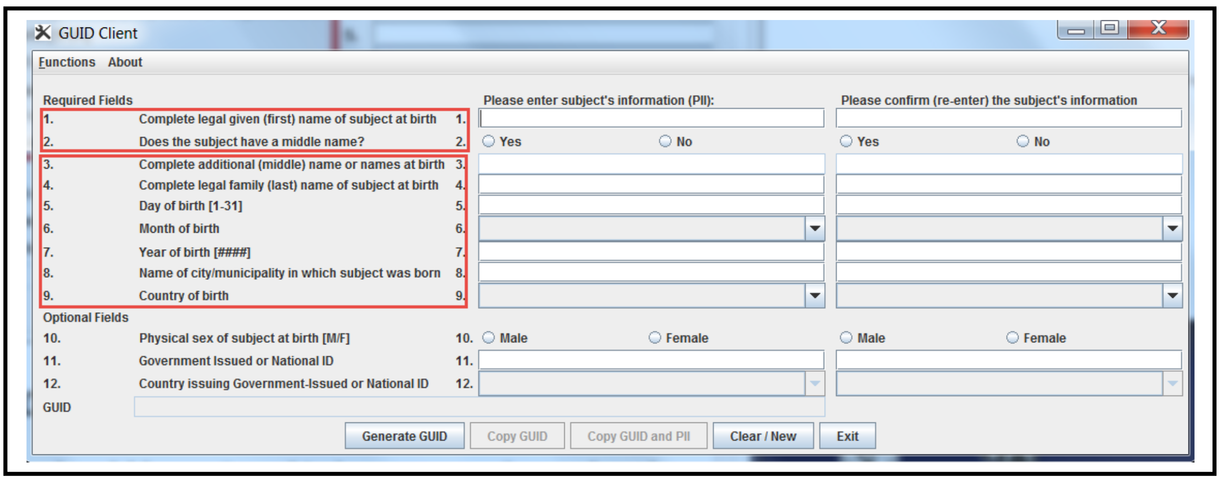
5. The **GUID Client Dialog Box** opens. **Enter the participant's information (Subject's Personal Identifiable Information** (PII)) into the dialog box. Re-enter the **Subject's Personal Identifiable Information** (PII) to confirm the subject's information.

   The required field names necessary to obtain a valid GUID are listed below:

   - ❖ Complete legal given (first) name of subject at birth
   - ❖ Select YES if the subject DOES HAVE a Middle Name, NO otherwise
   - ❖ Complete additional (middle) name or names at birth
   - ❖ Complete legal family (last) name of subject at birth
   - ❖ Day of birth [1—31]
   - ❖ Month of birth [January-December]
   - ❖ Year of birth [####]
   - ❖ Name of city/municipality in which subject was born
   - ❖ Country of birth

   The following are additional fields that can be used, but are not required:

   - ❖ Physical sex of subject at birth [Male/Female]
   - ❖ Government Issued or National ID number
   - ❖ Name of the country issuing the Government or National ID



6. To complete the GUID dialog box and obtain the GUID, complete the following steps, starting in the left column of the dialog box:

a) Enter in the complete legal given (first) name of subject at birth.

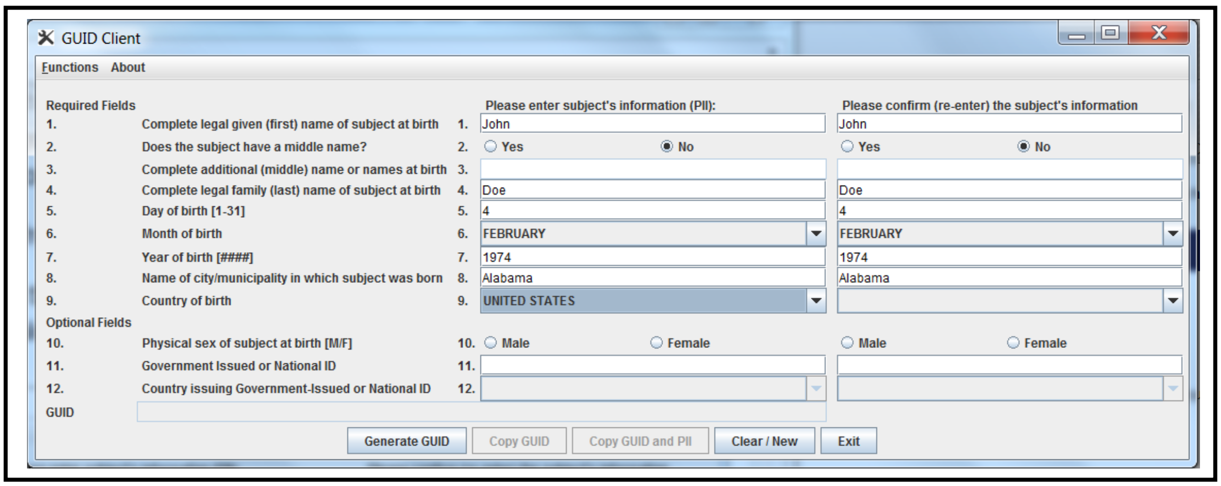
b) Select Yes or No depending on whether or not the subject has a middle name. If yes, enter information in field 3.

c) Complete the required fields 4-9;

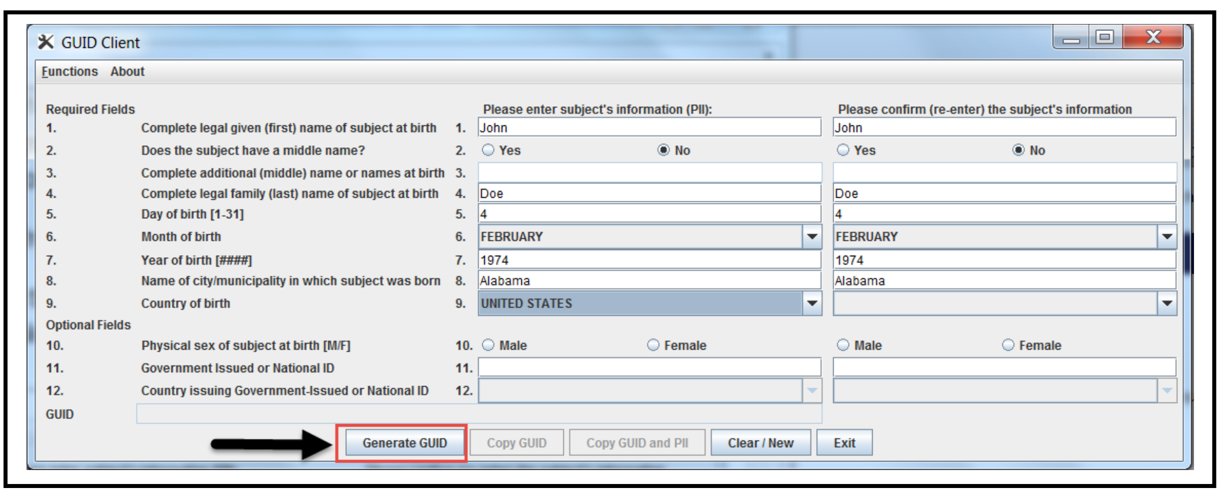
d) If information is available, complete the optional fields 10-12. Enter the subject's physical sex at birth into #10 field, the government issued or national ID number into #11 field (note that the list box in #12 field becomes available once data is entered into #11);

e) Select the country of issued ID from the list provided.

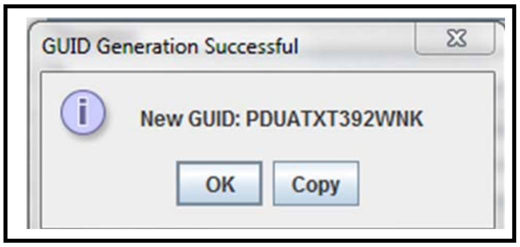
f) Enter the same information into the right column of the dialog box as shown below:



7. Click the **Generate GUID** button. Note: Spaces, hyphens and apostrophes can be used in the non-numeric GUID fields in the dialog box and are stripped silently by the application



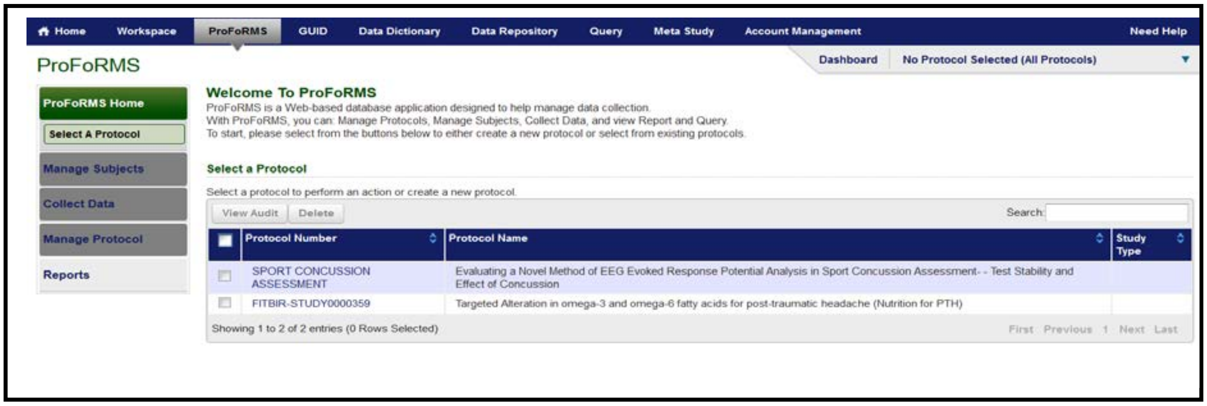
8. A popup window with the GUID information will appear if there was successful GUID generation. Click the **OK** button.



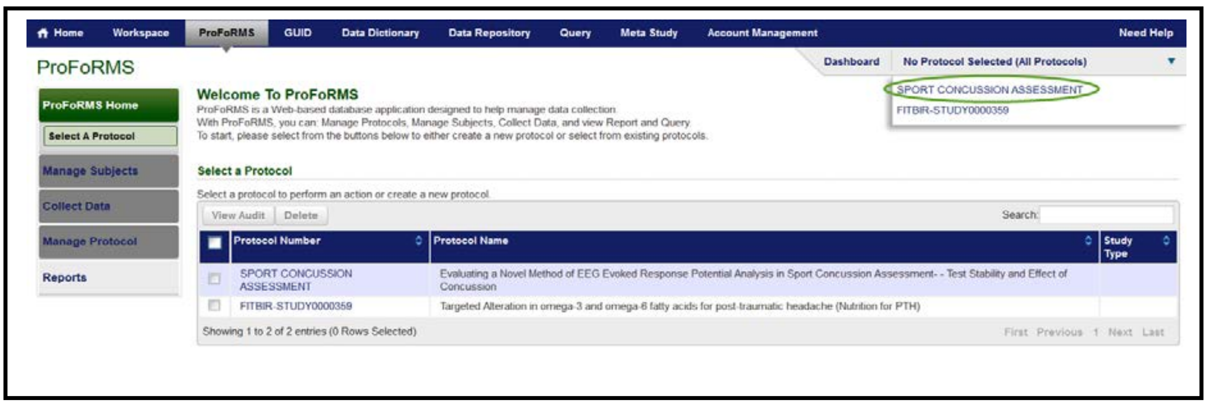
3.6.3 Edit Subject Information

To access this feature: Perform the following actions:

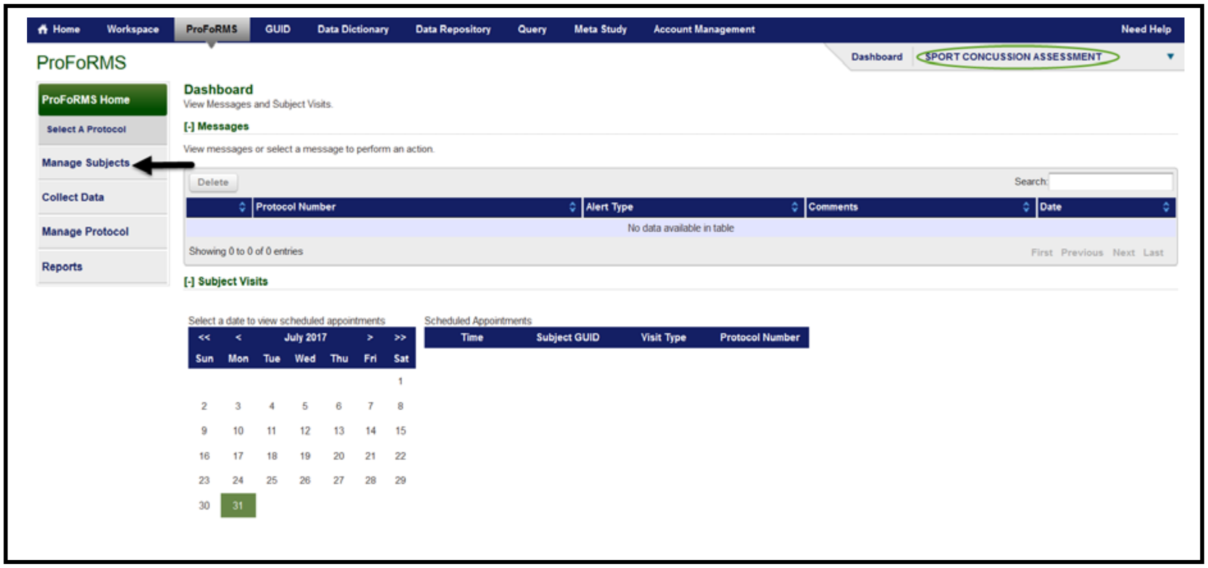
1. Navigate to the **ProFoRMS** module



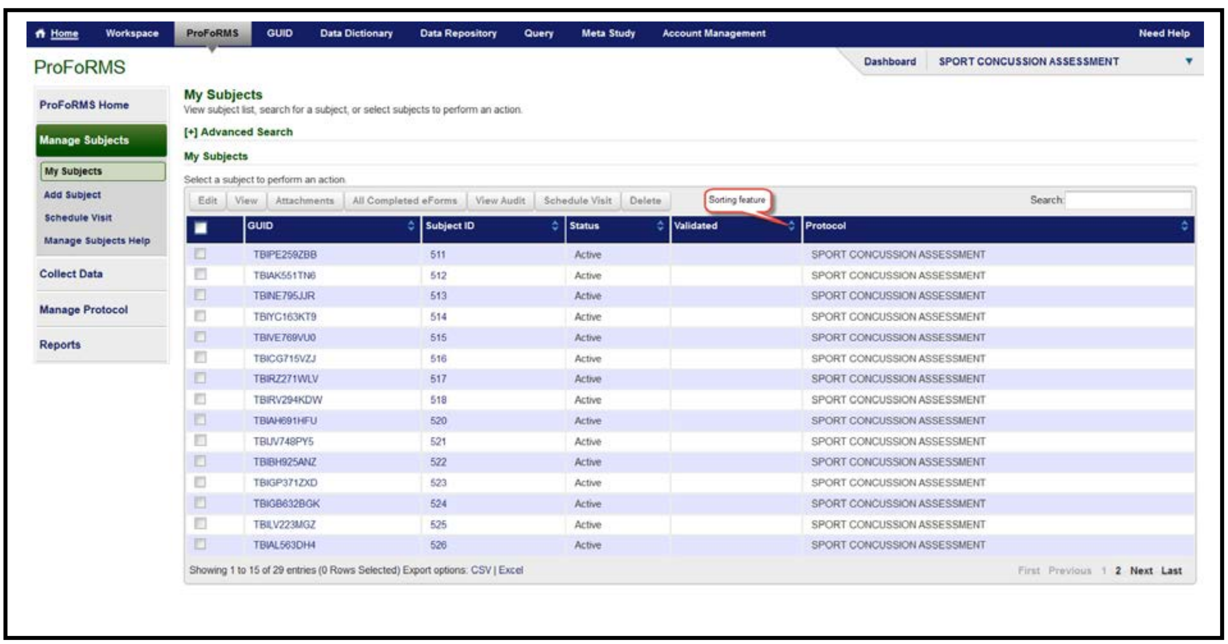
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



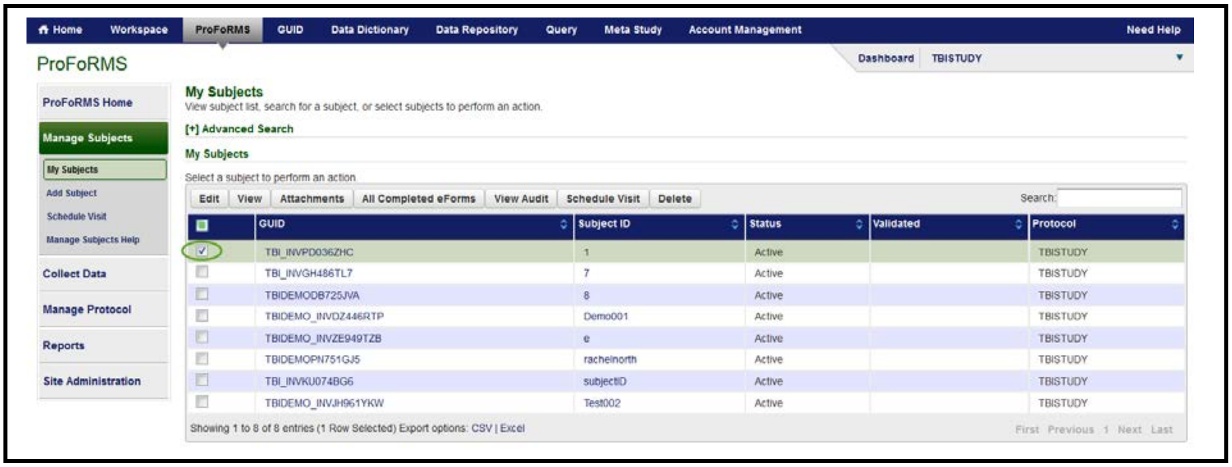
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



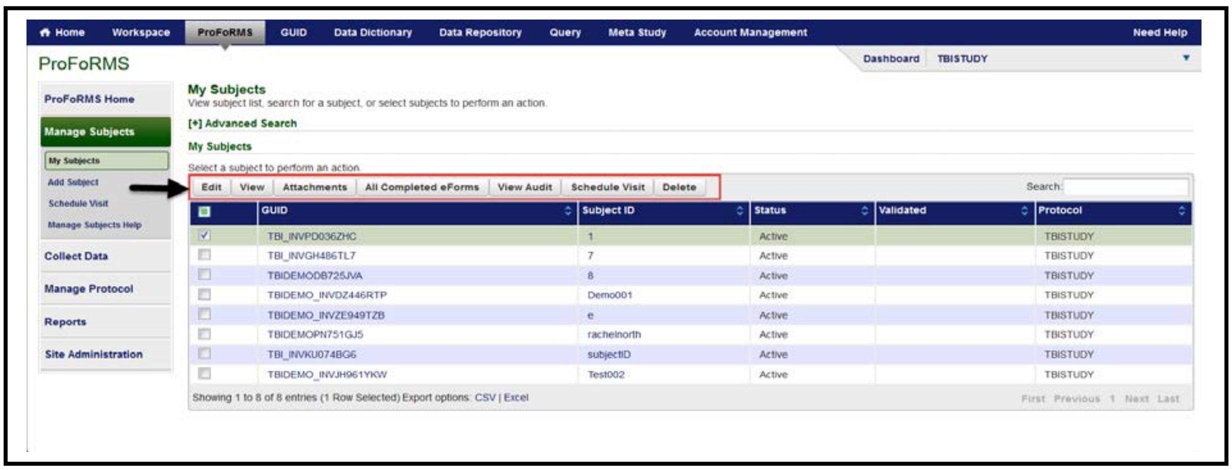
4. **My Subjects** page appears within a list that can be sorted by clicking on the arrows on any field using the symbol. While in the Subject view, you may *View Subject lists*, *Search for Subject* or *Select Subjects* to perform any desired action.



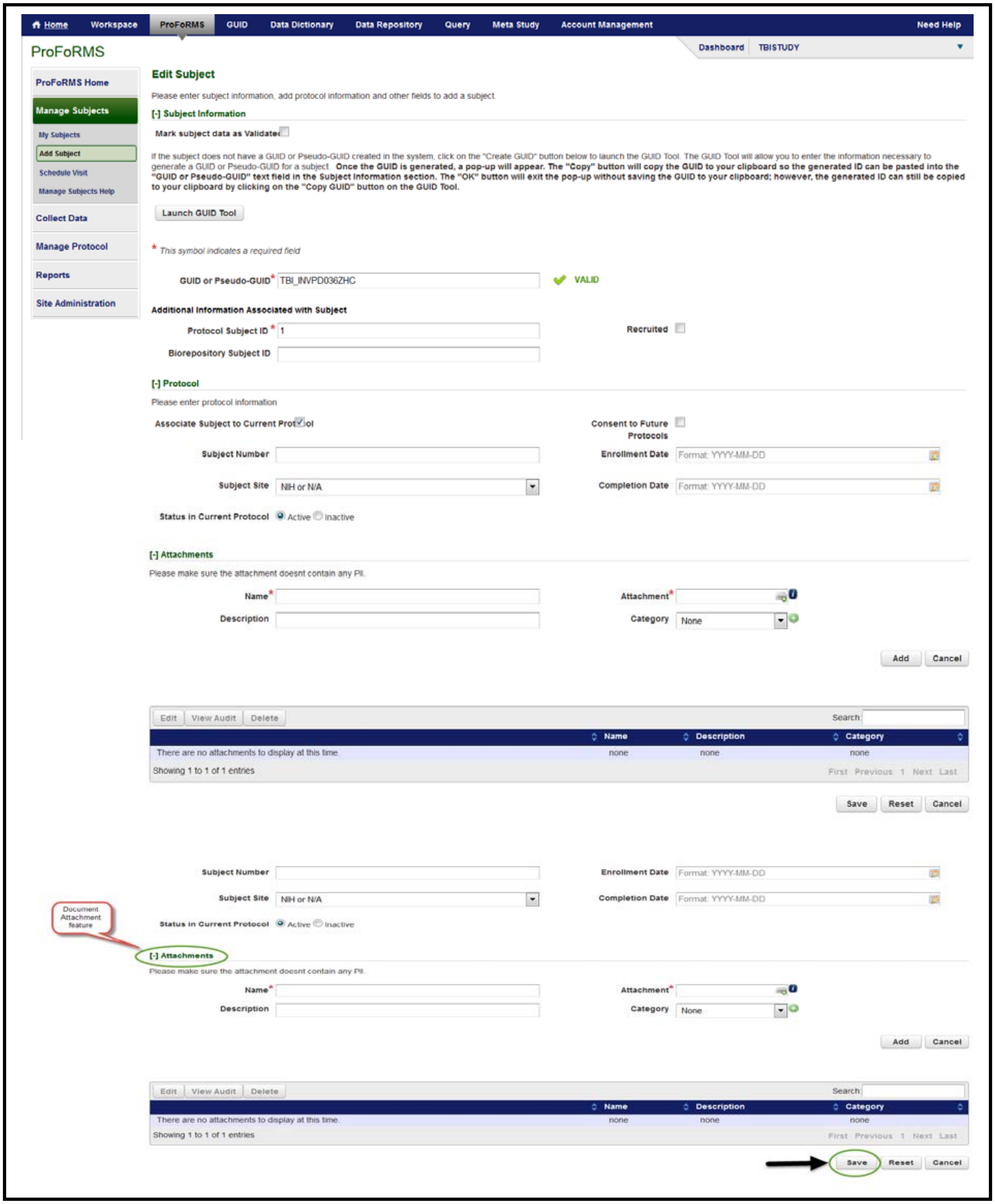
5. Select a **Subject** from the list of subjects to edit.



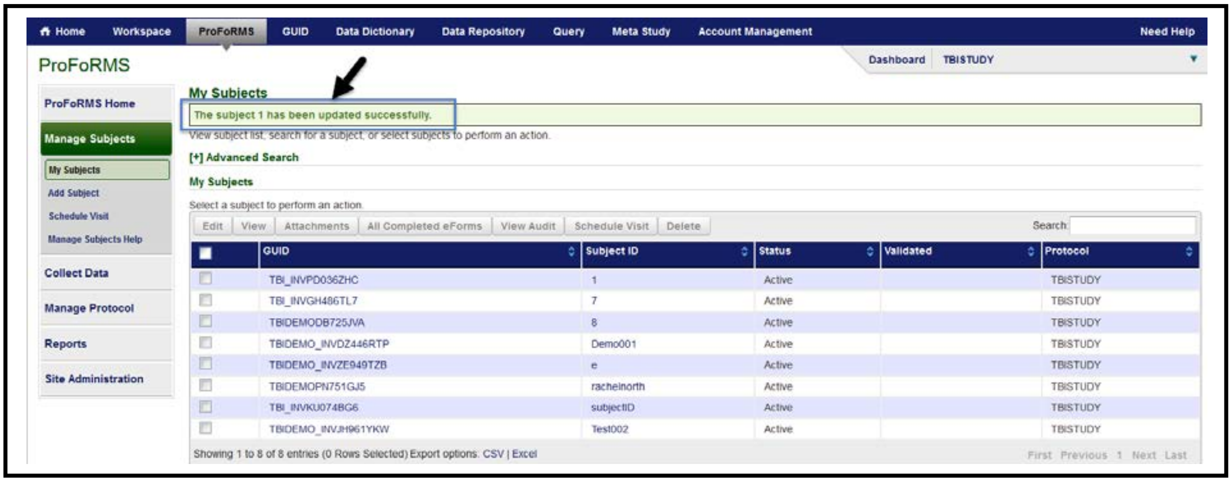
6. Click the **Edit** button from the action bar.



7. <u>**NOTE**</u>: Even though the link on the left hand side says "**Add Subject**," by clicking on the "**Edit**" button in the "**My Subjects**" page, it will bring the user to the "Edit Subject" page, where any required fields that was needed to create a subject (i.e. GUID or Pseudo-GUID, Protocol Subject ID) will already be populated.



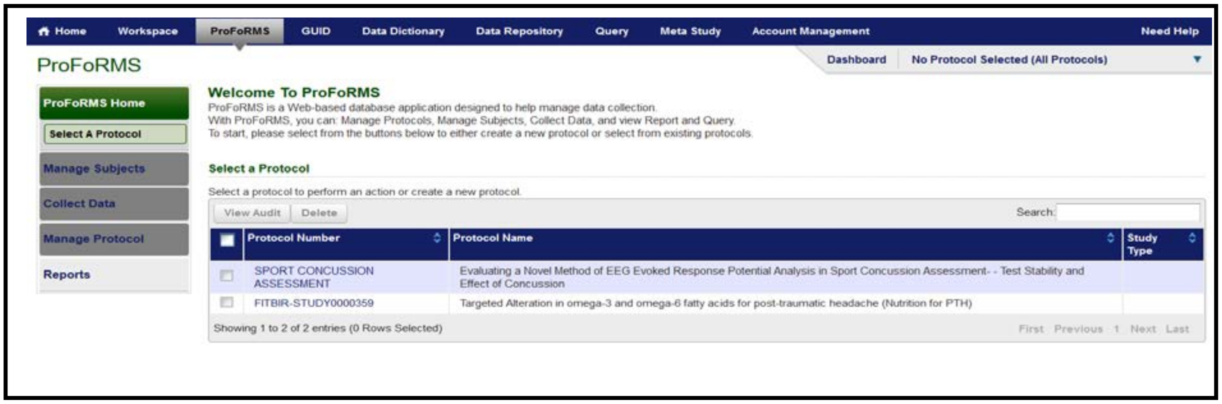
8. The **My Subject** page appears with at confirmation of the changes.



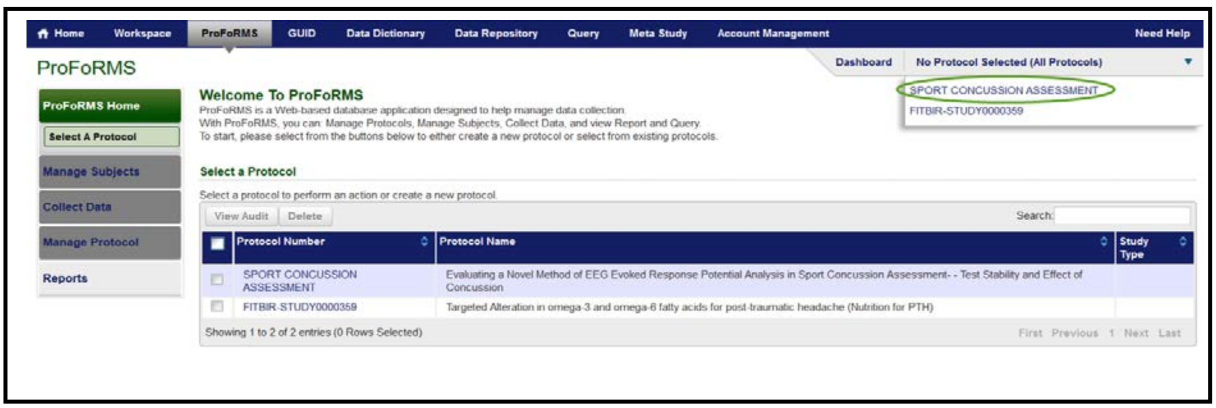
3.6.4 View Subject Information

To View Subject Information: Perform the following actions:

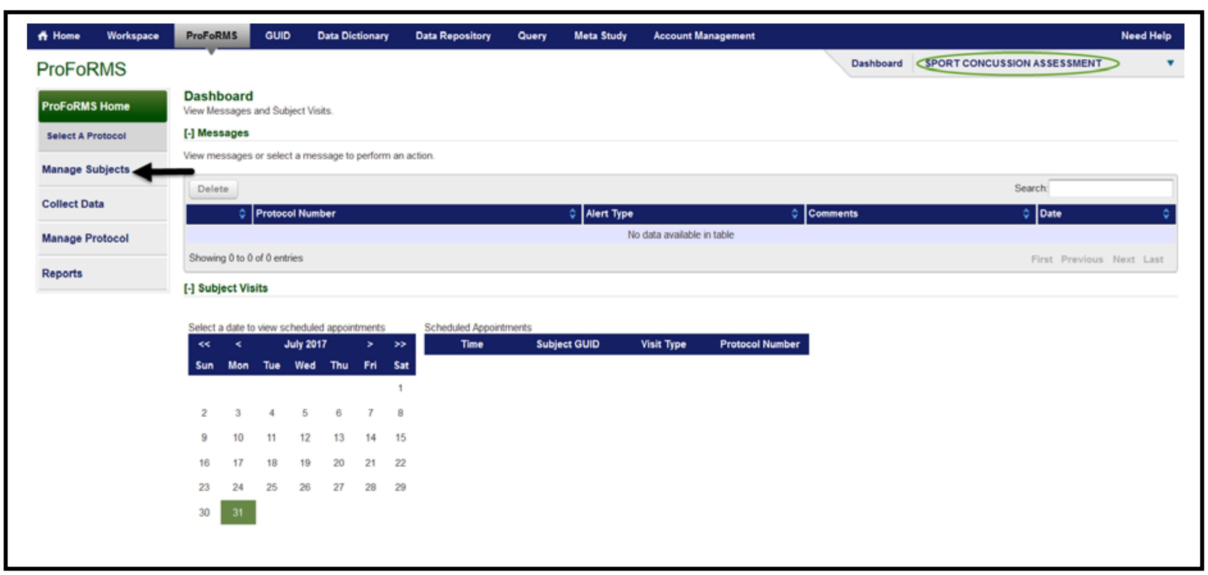
1. Navigate to the **ProFoRMS** module



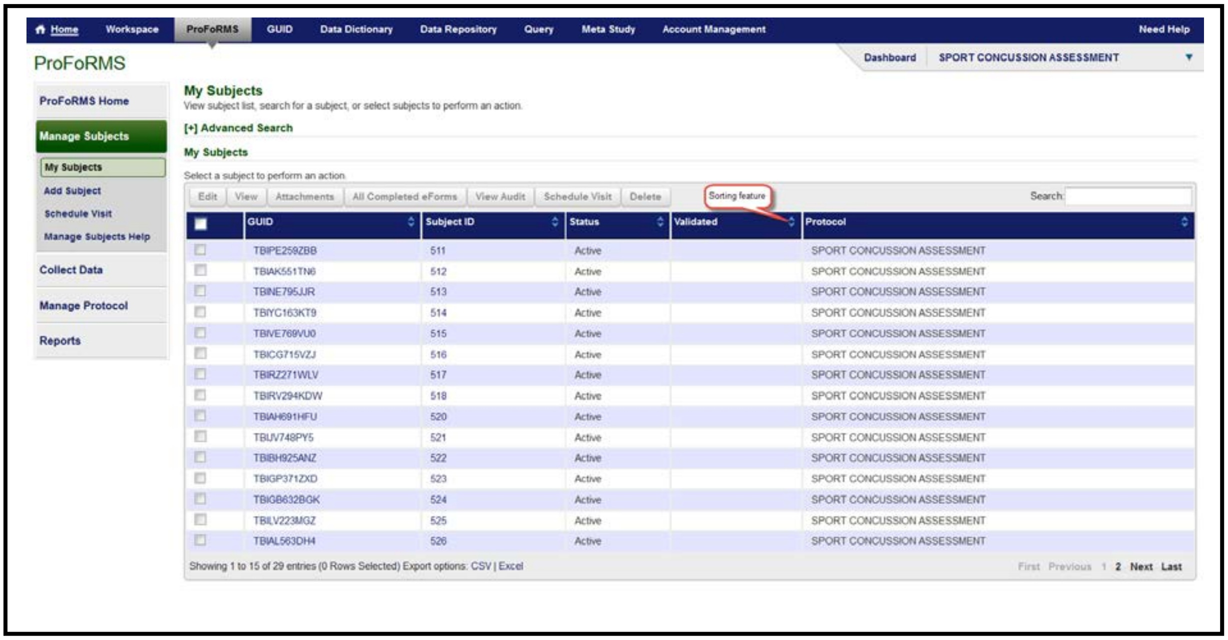
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



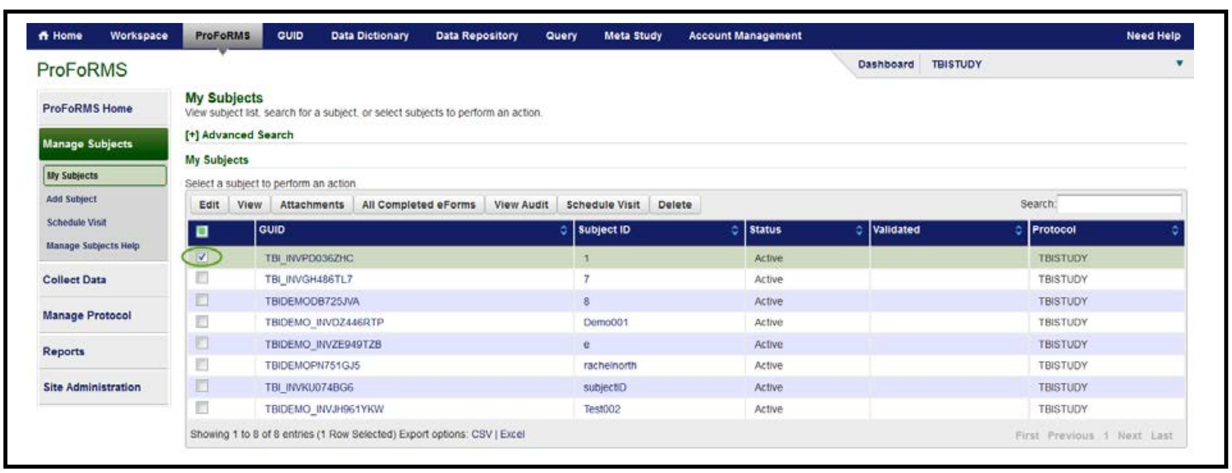
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



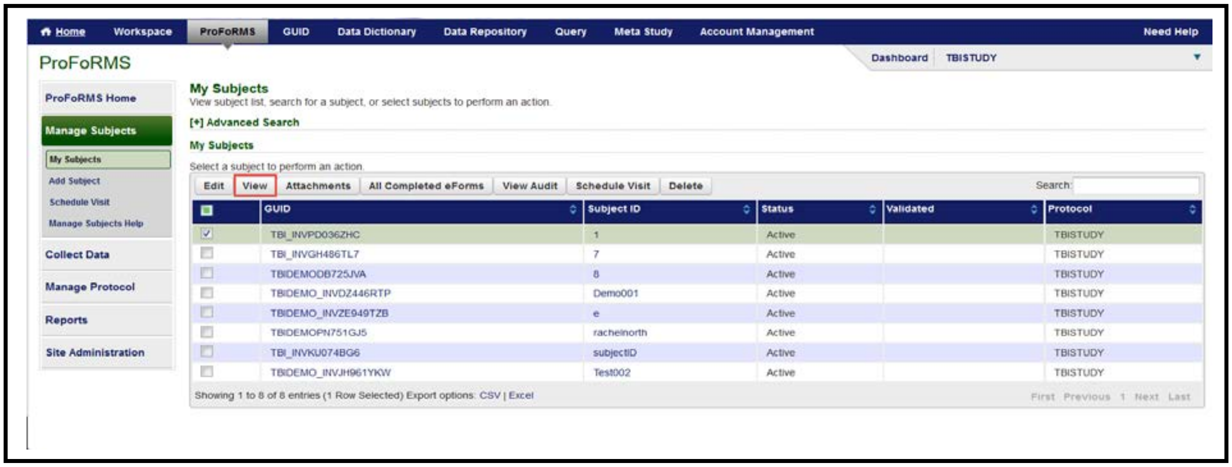
4. **My Subjects** page appears with in a list that can be sorted by clicking on the arrows on any field using the symbol. While in the Subject view, you may *View Subject lists*, *Search for Subject* or *Select Subjects* to perform any desired action.



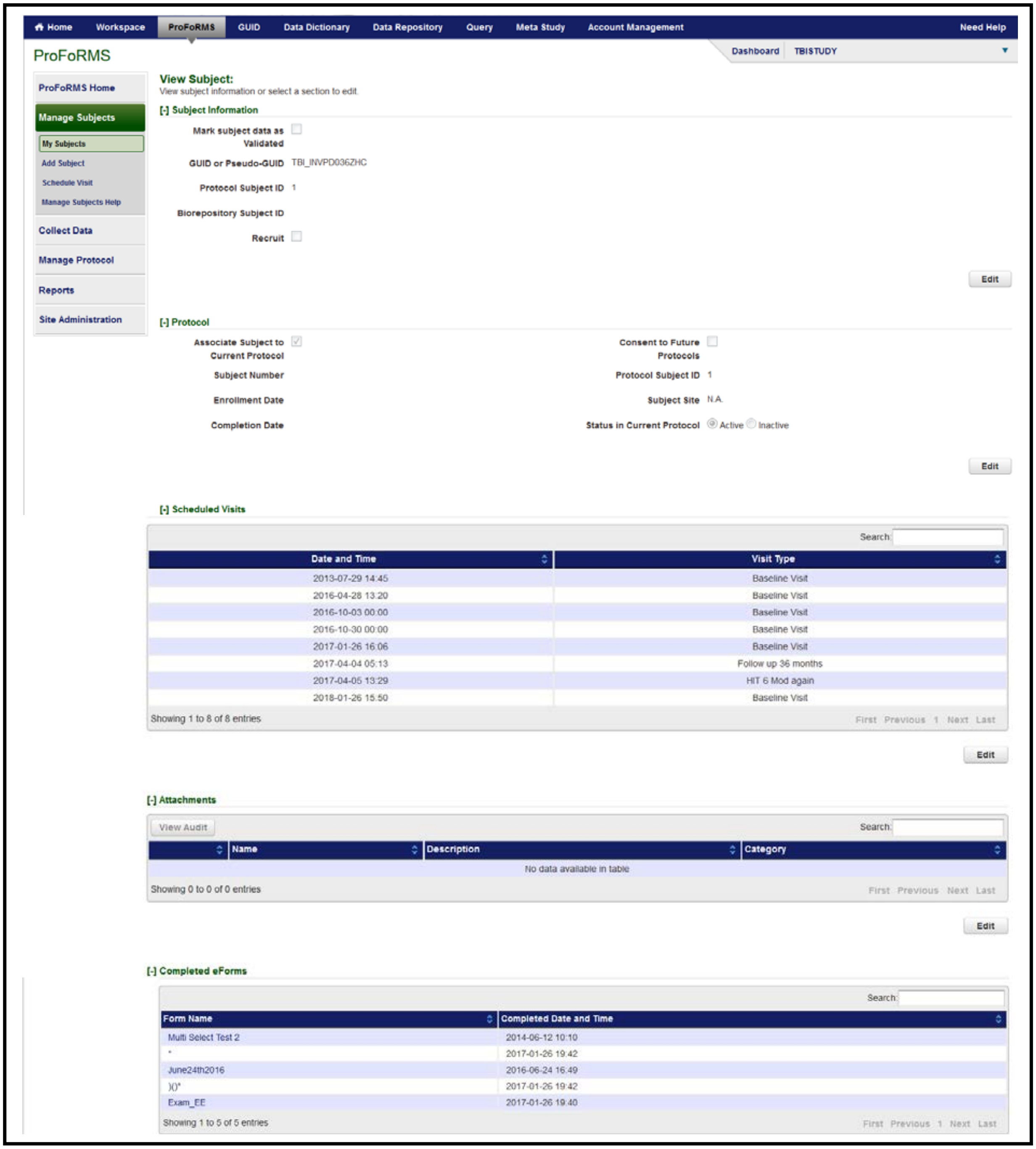
5. Select a **Subject** from the list of subjects to edit.



6. Click the **View** button from the action bar.



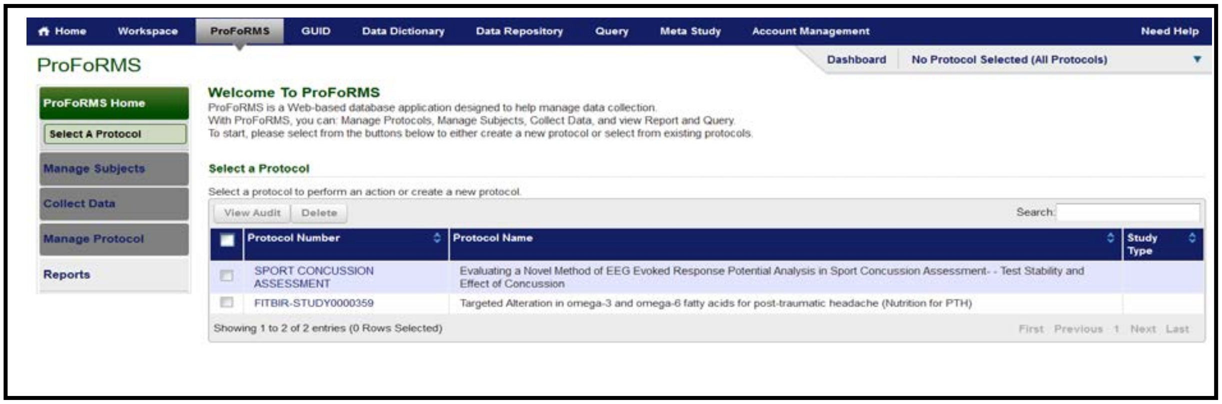
7. The View Subject Information appears showing the various sections: Subject Information, Protocol, Scheduled Visits, Attachments and Completed eForms.



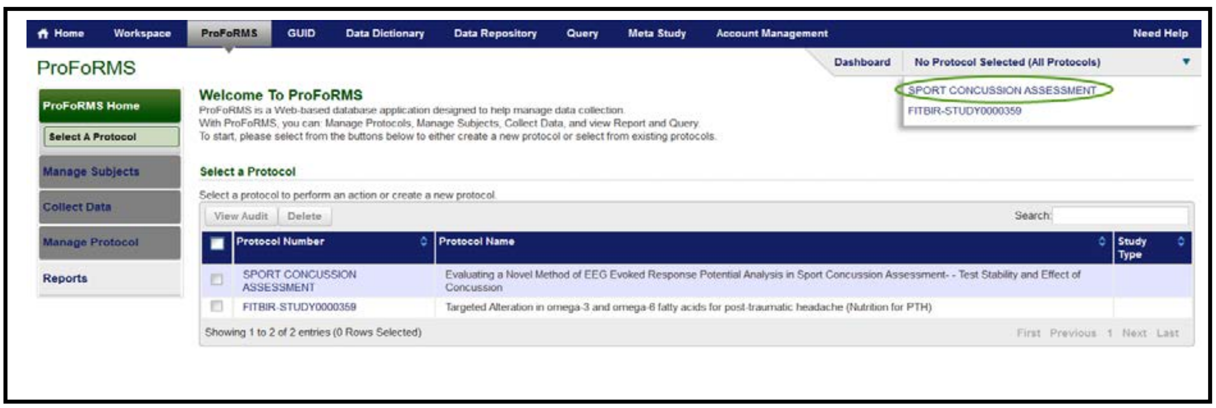
3.6.5 Scheduling Visits

To Schedule a visit: Perform the following actions:

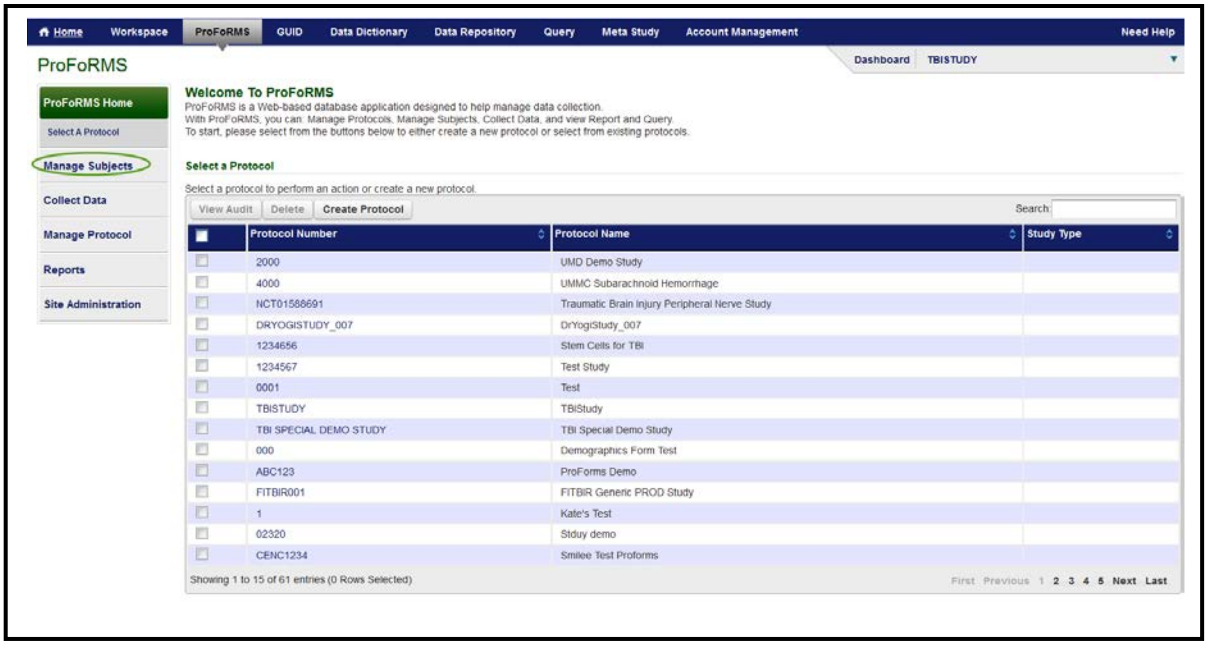
1. Navigate to the **ProFoRMS** module



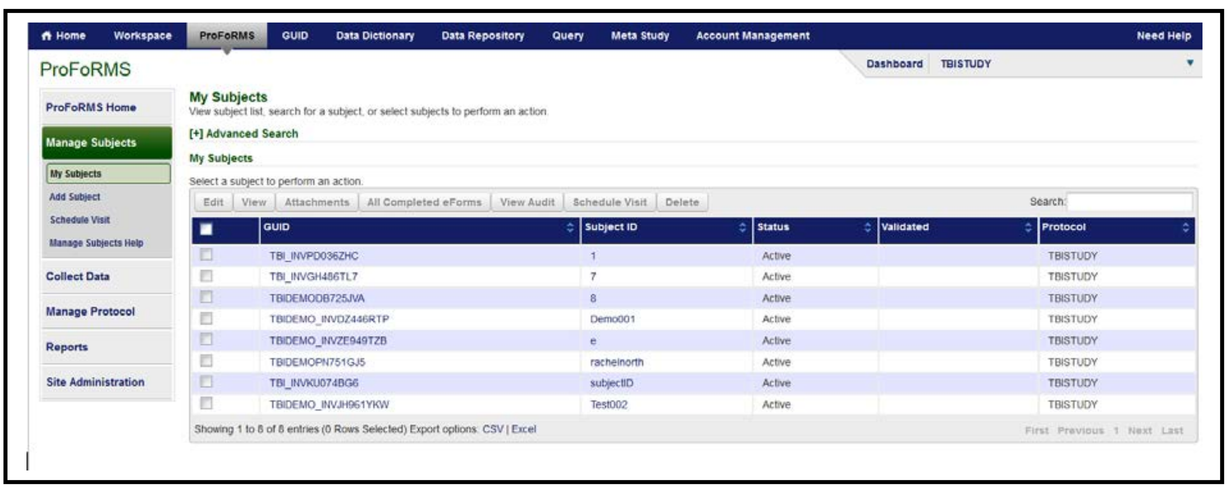
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.

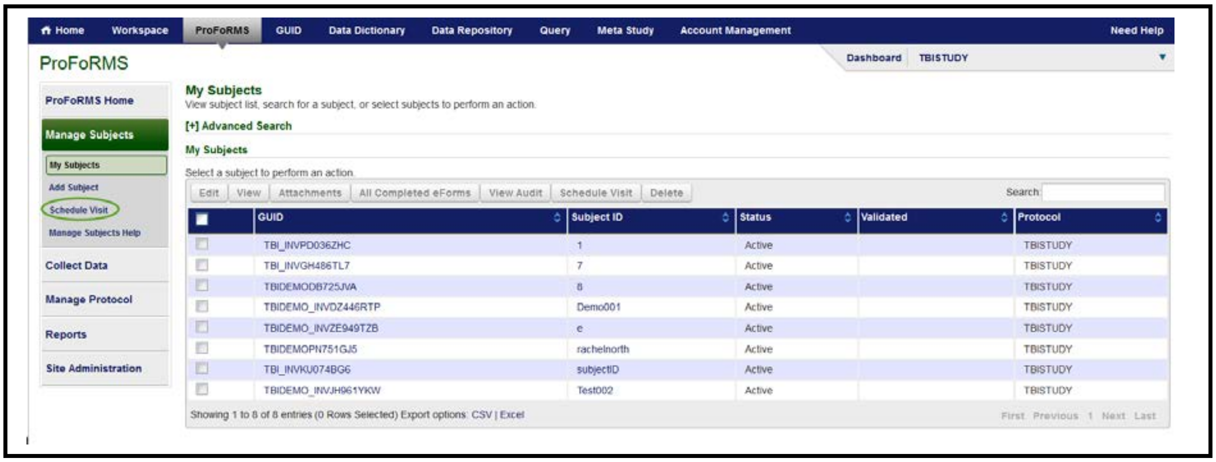


4. **My Subjects** page appears with in a list that can be sorted by clicking on the arrows on any field using the symbol.

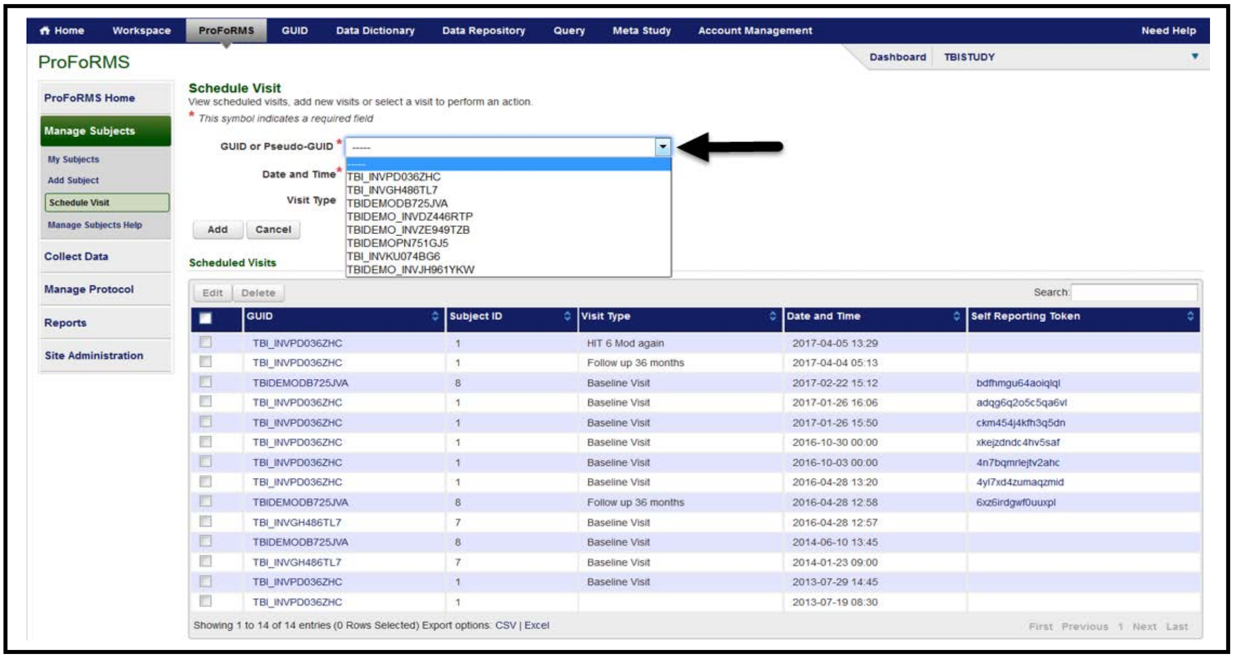


<u>**NOTE**</u>: You may also be able to schedule a visit for a specific subject by going to "**My Subjects**" page, selecting subject by clicking on the checkbox (this will enable numerous buttons such as edit, view, etc.), then select "**Schedule Visit**" button. This will direct you to the '**Schedule Visit**" page, with the GUID/Pseudo-GUID that was selected prepopulated in the GUID/Pseudo-GUID field.

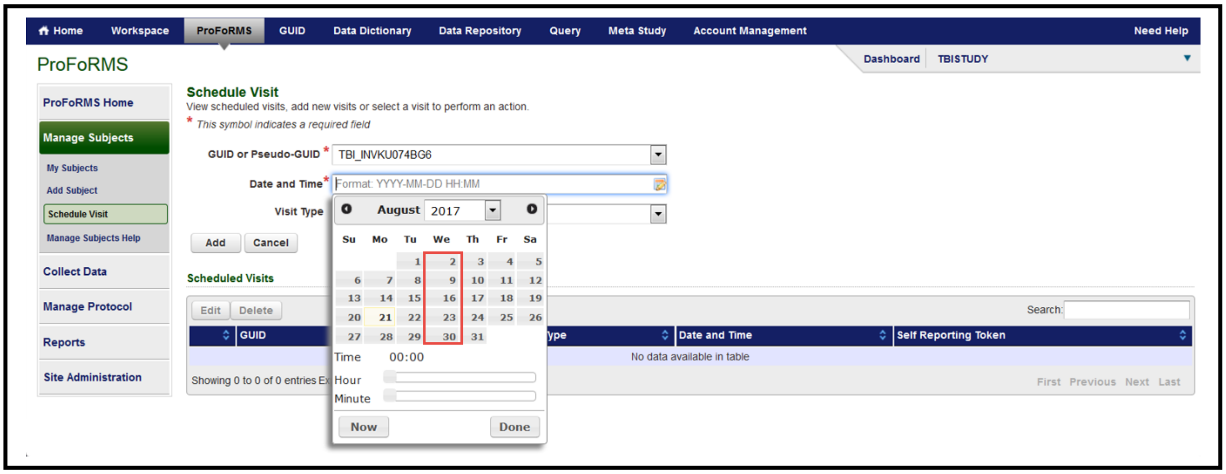
5. Click the **Schedule Visit** tab on the left-side tool bar.



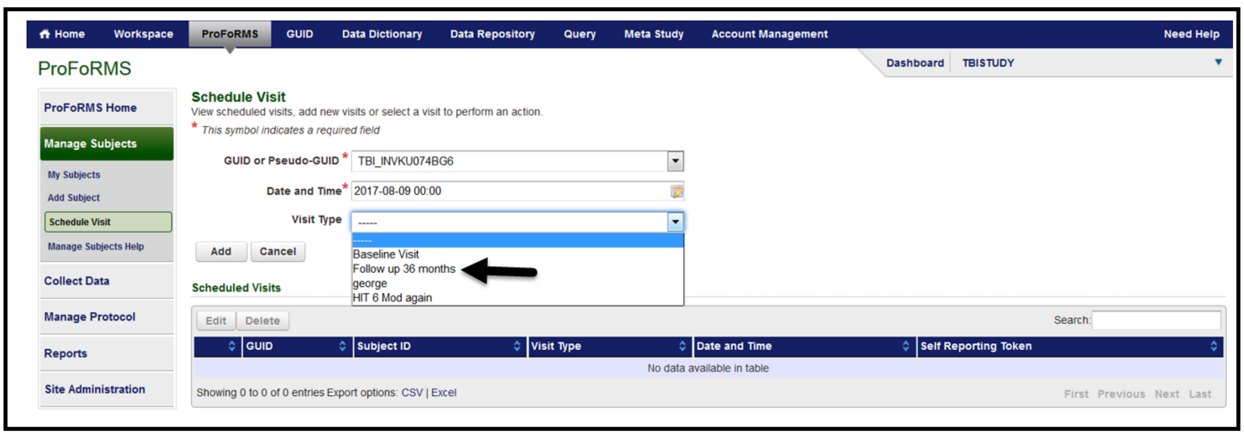
6. Select the **GUID or Pseudo-GUID** of the Subject you would like to schedule a visit from the GUID or Pseudo-GUID drop-down menu.



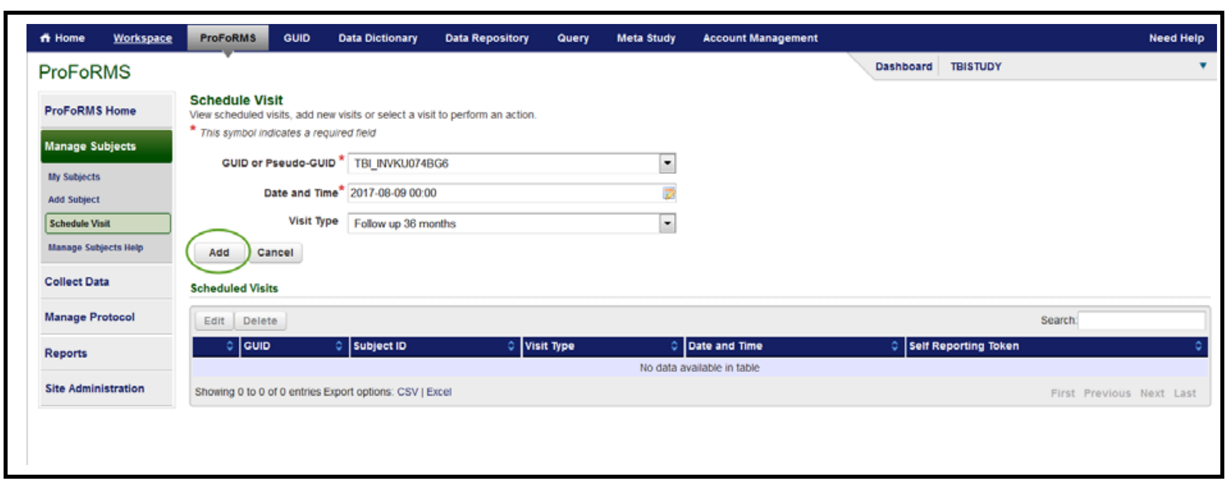
7. Click the **Calendar**  icon to choose the desired **Date** and **Time** for the visit.



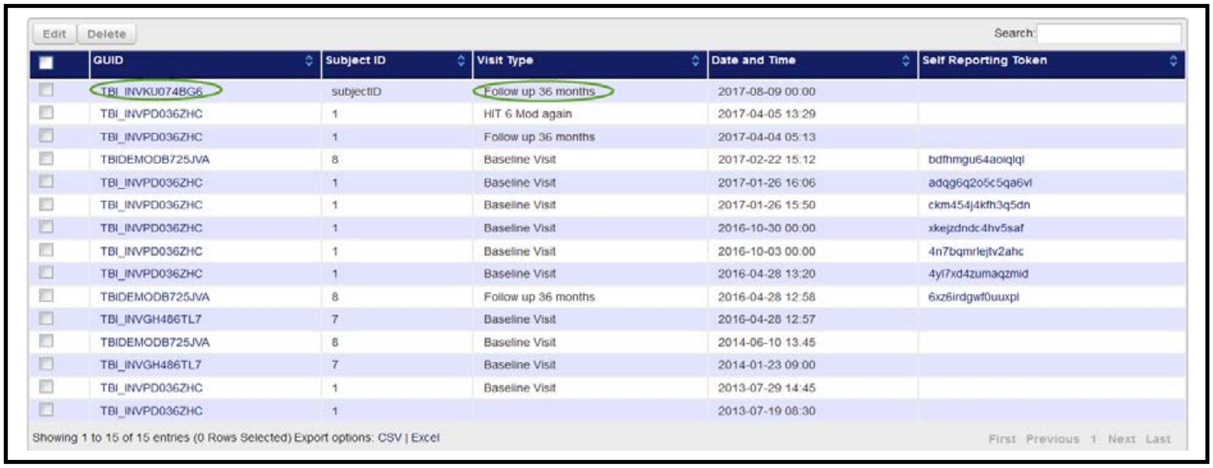
8. Choose the **Visit Type** from the drop-down menu.



9. Click the **Add** button.



10. The newly scheduled visit will be displayed on the Scheduled Visits list as shown below:



Edit | Delete

Search:

GUID	Subject ID	Visit Type	Date and Time	Self Reporting Token
TBI_INVKU074BG6	subjectID	Follow up 36 months	2017-08-09 00:00	
TBI_INVPD036ZHC	1	HIT 6 Mod again	2017-04-05 13:29	
TBI_INVPD036ZHC	1	Follow up 36 months	2017-04-04 05:13	
TBIDEMODB725JVA	8	Baseline Visit	2017-02-22 15:12	bdfhmgu64aoiqlql
TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 16:06	adqg6q2o5c5qa6vl
TBI_INVPD036ZHC	1	Baseline Visit	2017-01-26 15:50	ckm454j4kfh3q5dn
TBI_INVPD036ZHC	1	Baseline Visit	2016-10-30 00:00	xkejzdndc4hv5saf
TBI_INVPD036ZHC	1	Baseline Visit	2016-10-03 00:00	4n7bqmrlejtv2ahc
TBI_INVPD036ZHC	1	Baseline Visit	2016-04-28 13:20	4yl7xd4zumaqzmid
TBIDEMODB725JVA	8	Follow up 36 months	2016-04-28 12:58	6xz6irdgwf0uuxpl
TBI_INVGH486TL7	7	Baseline Visit	2016-04-28 12:57	
TBIDEMODB725JVA	8	Baseline Visit	2014-06-10 13:45	
TBI_INVGH486TL7	7	Baseline Visit	2014-01-23 09:00	
TBI_INVPD036ZHC	1	Baseline Visit	2013-07-29 14:45	
TBI_INVPD036ZHC	1		2013-07-19 08:30	

Showing 1 to 15 of 15 entries (0 Rows Selected) Export options: CSV | Excel

First Previous 1 Next Last

ICON KEY

Notes

Important Information

Things to Note:

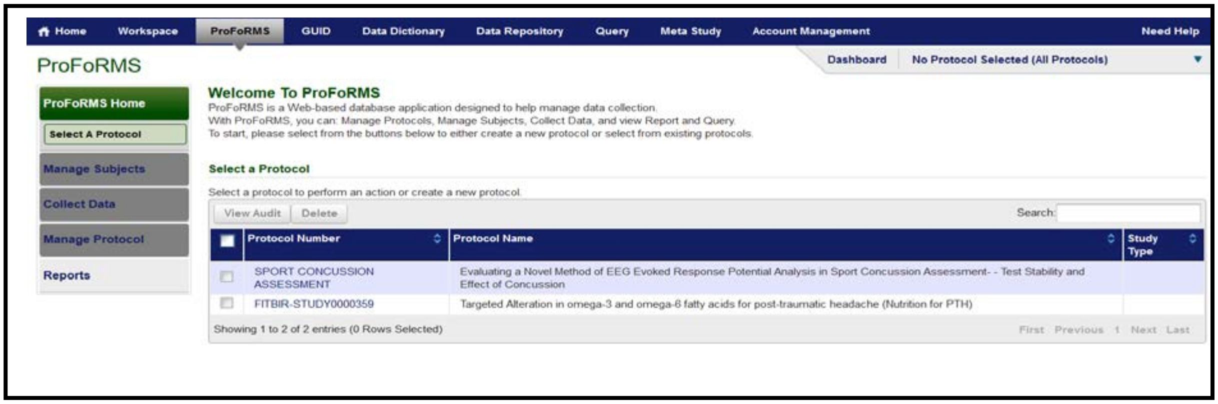
- Another pathway to scheduling a visit:
  - Go to **My Subject**
  - Select any GUID by clicking on the checkbox
  - Click the Schedule Visit button, which will be activated once a GUID is selected
- This action will bring the user to the Schedule Visit page where you can schedule a visit
- This step is recommended as the User can search/filter for a specific GUID through the search bar instead of finding the GUID using the drop down-menu.

3.6.6 Editing Scheduled Visits

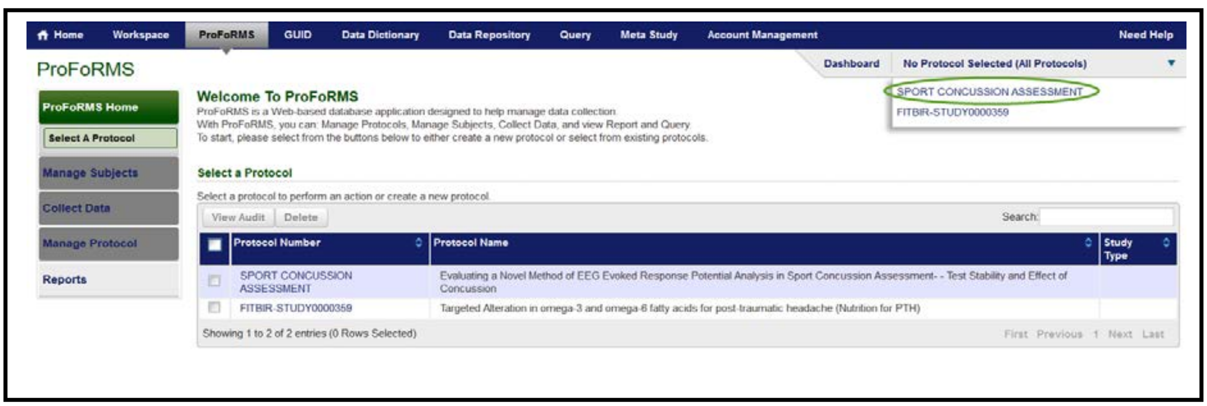
The **Schedule Visits** feature provides you with the ability to schedule visits as well as perform other functions such as **Edit Visits**, **Delete Visits**.

To edit scheduled visits: Perform the following actions:

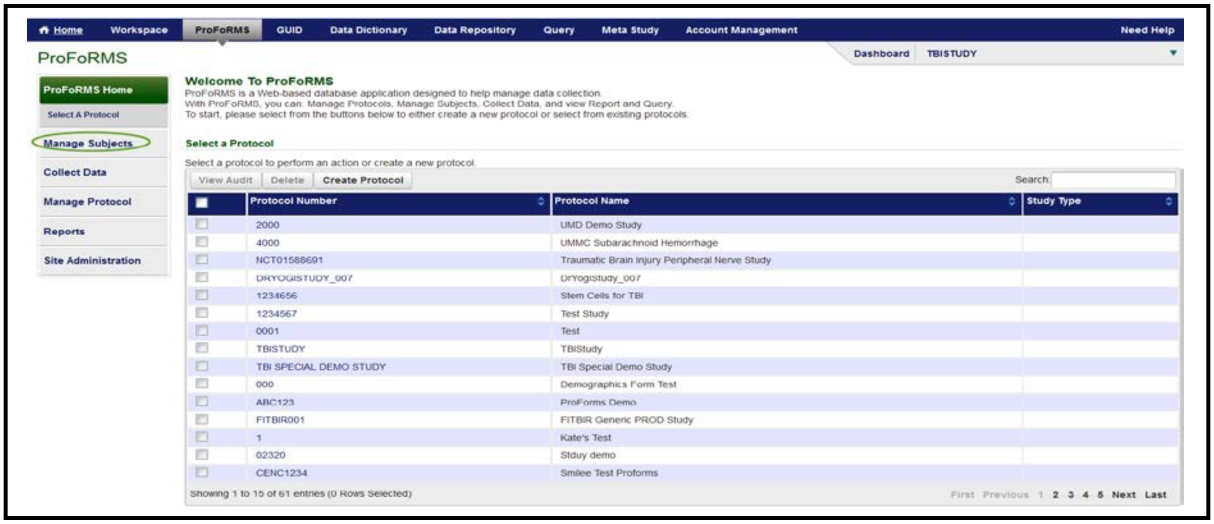
1. Click the **ProFoRMS** tab at the top of the screen



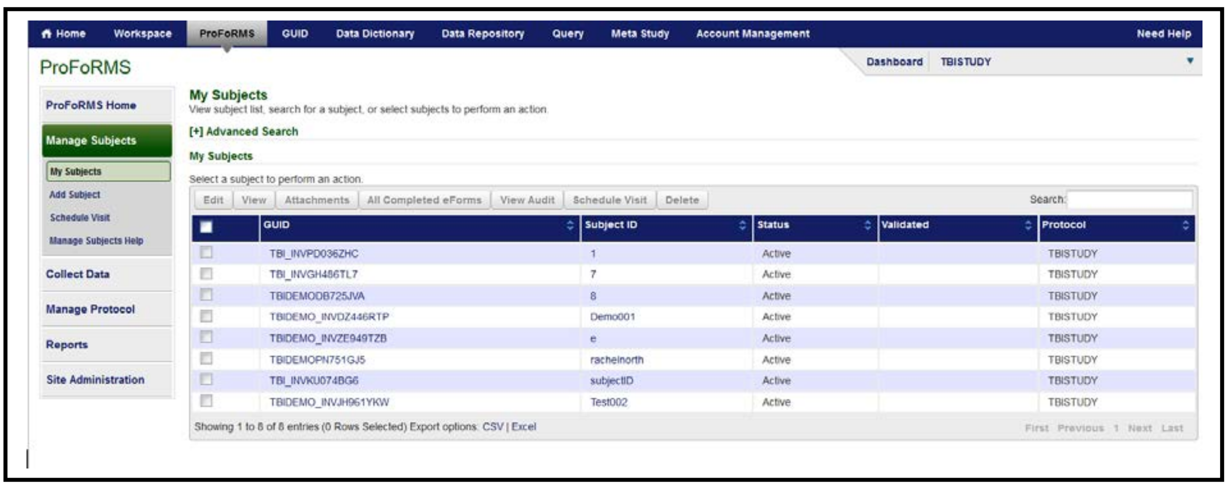
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



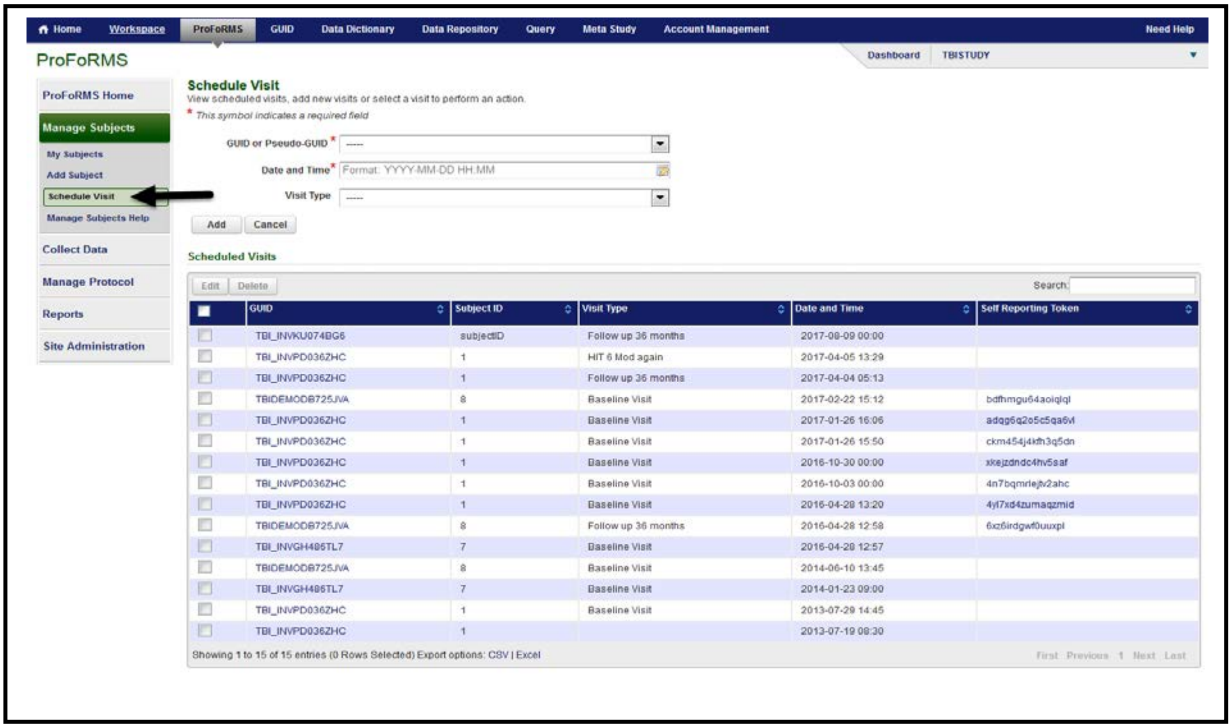
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



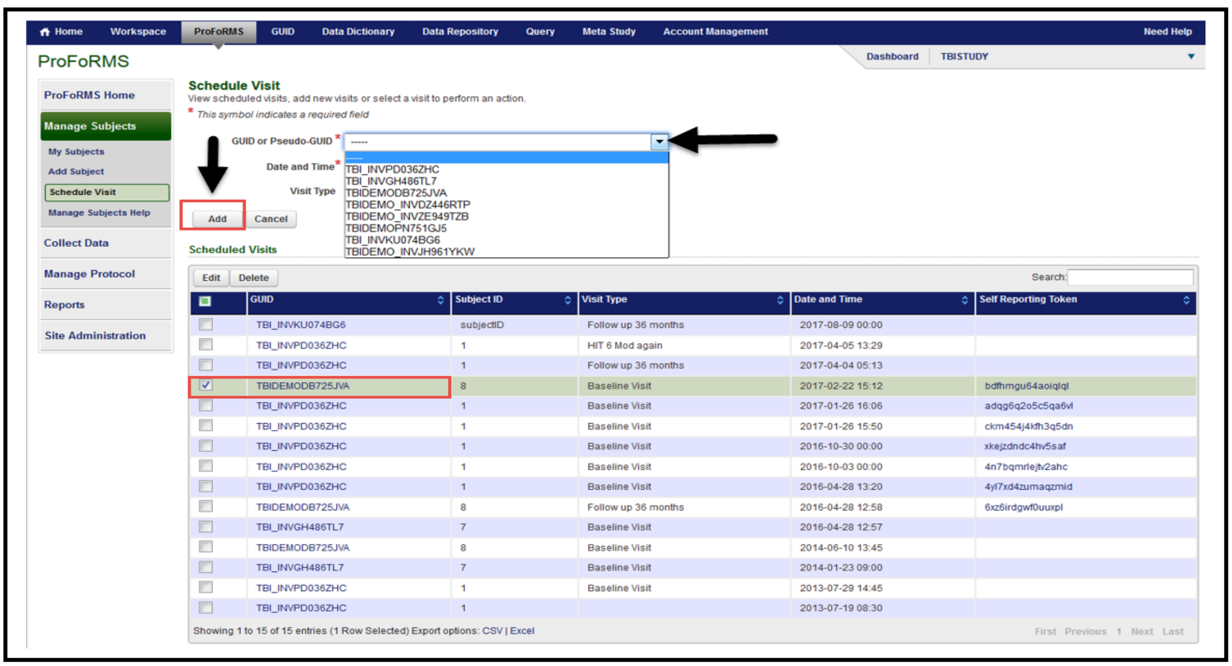
4. **My Subjects** page appears with in a list that can be sorted by clicking on the arrows on any field using the  symbol.



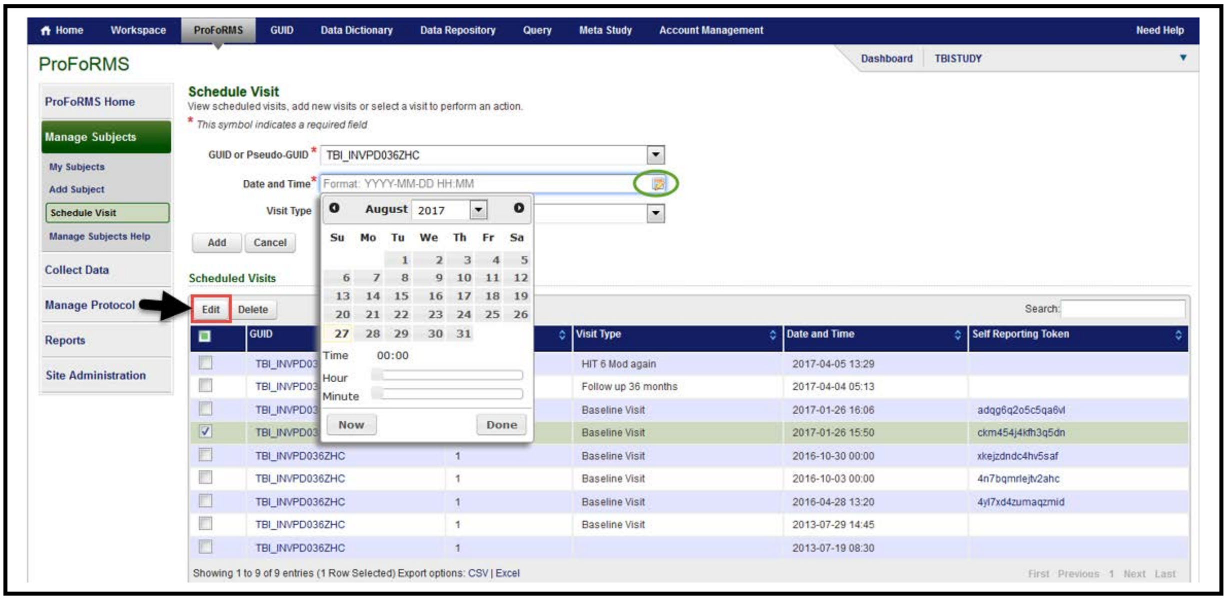
5. Click the **Schedule Visit** tab on the left-side tool bar.



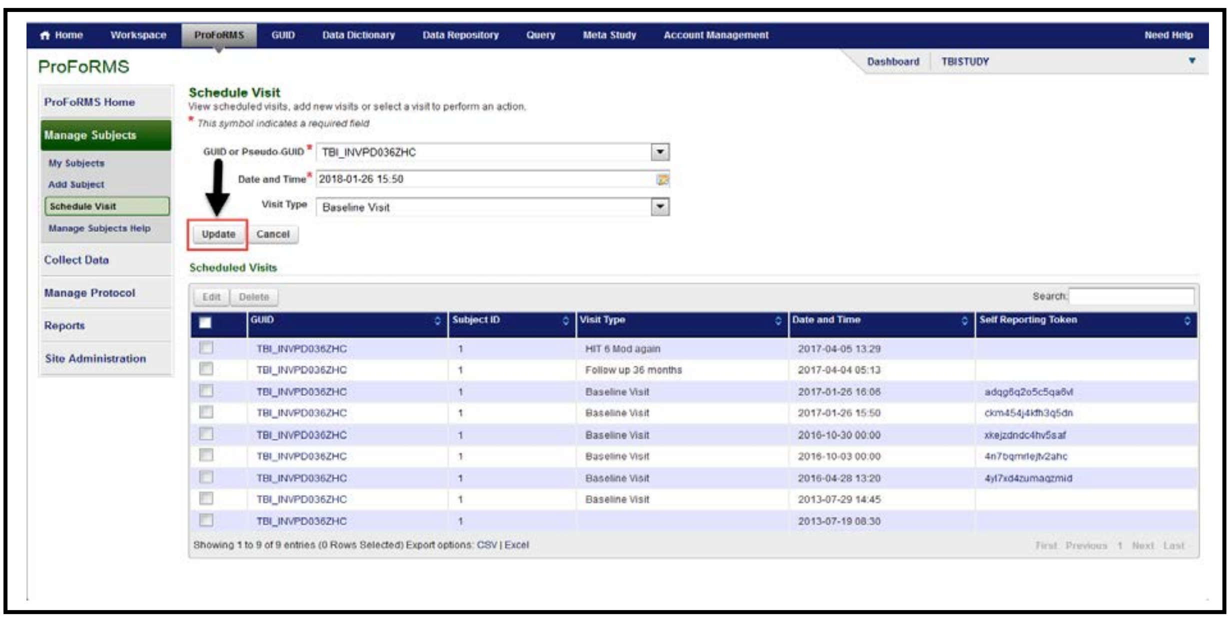
6. The **Schedule Visit** page appears from where you can ***View Scheduled Visits***, ***Add New View Visits,*** or ***Select a Visit*** to perform an action. Select the **GUID** of the Subject you would like to schedule a visit from the **GUID** or **Pseudo-GUID** drop-down menu.



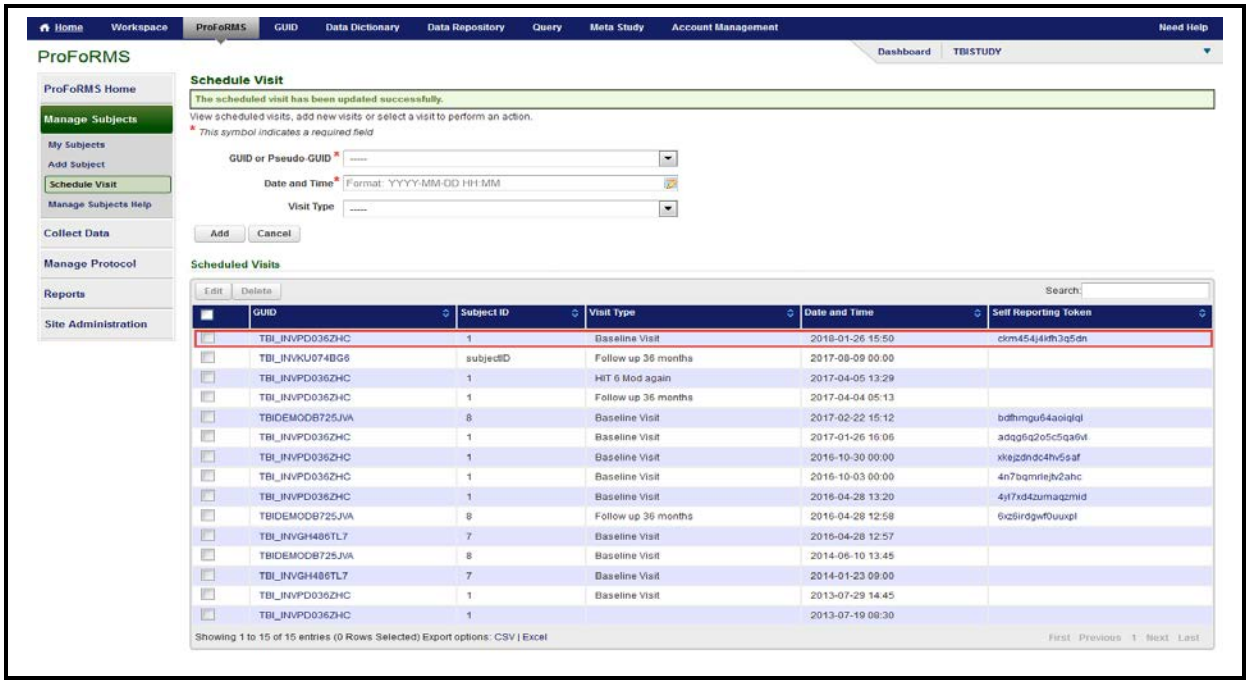
7. Click on the **Edit** button to update as needed. Using the **Calendar** icon to choose the desired **Date** and **Time** for the visit



8. Click the **Update** button to complete the edit action.



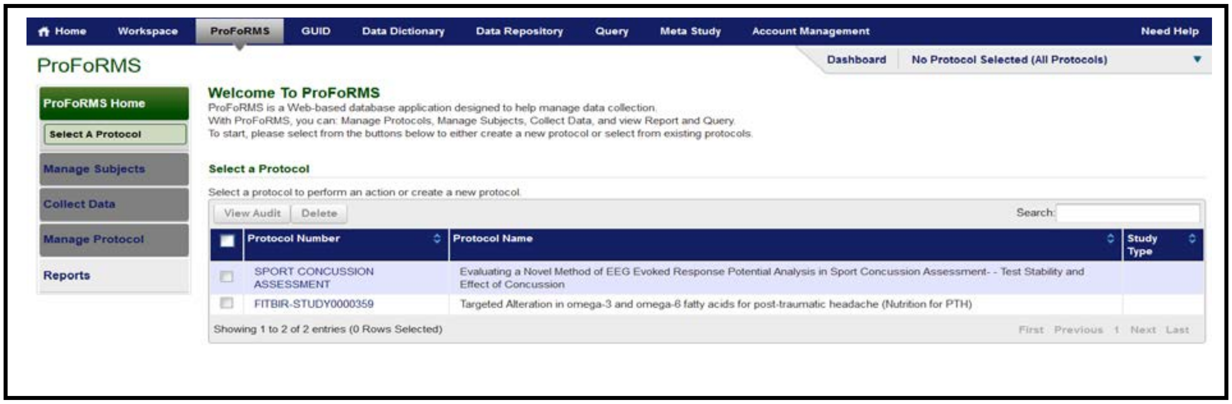
9. The newly scheduled visit will be displayed on the Scheduled Visits list as shown below:



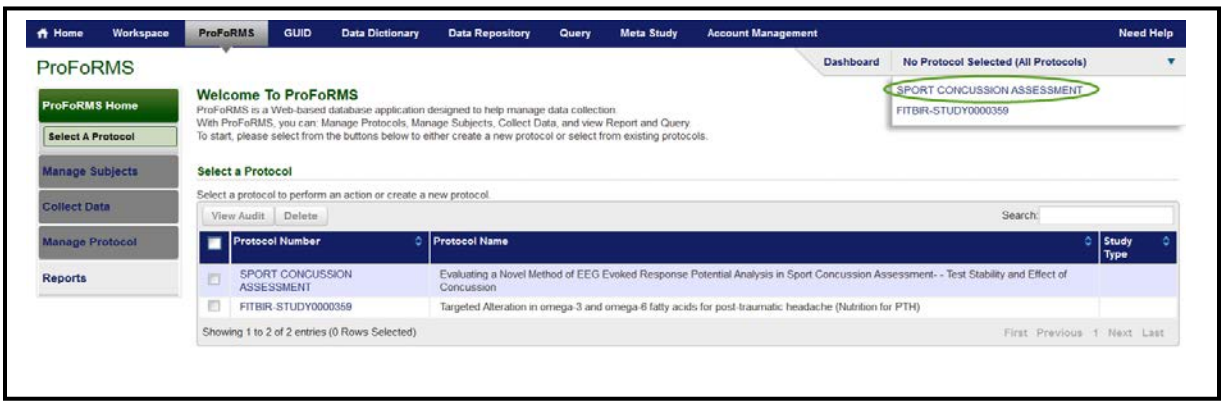
3.6.7 Deleting Scheduled Visits

To Delete Scheduled Visits: Perform the following actions:

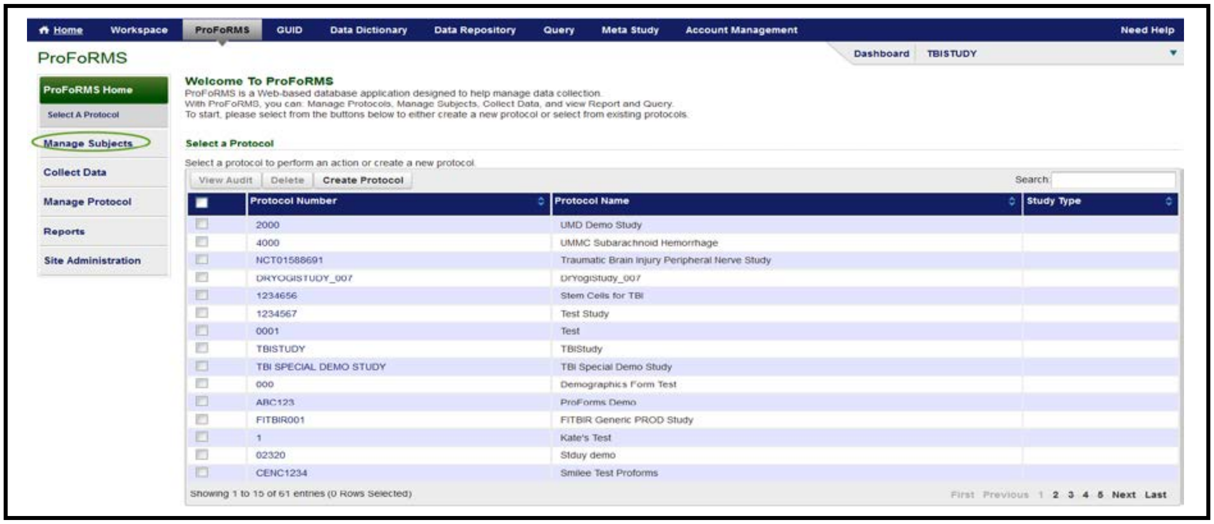
1. Click the **ProFoRMS** tab at the top of the screen



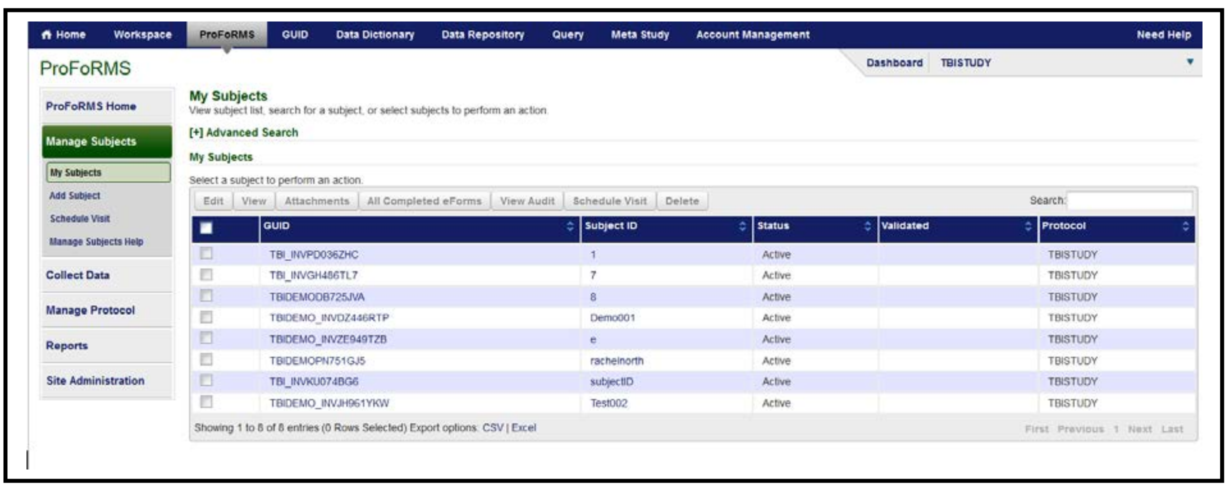
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



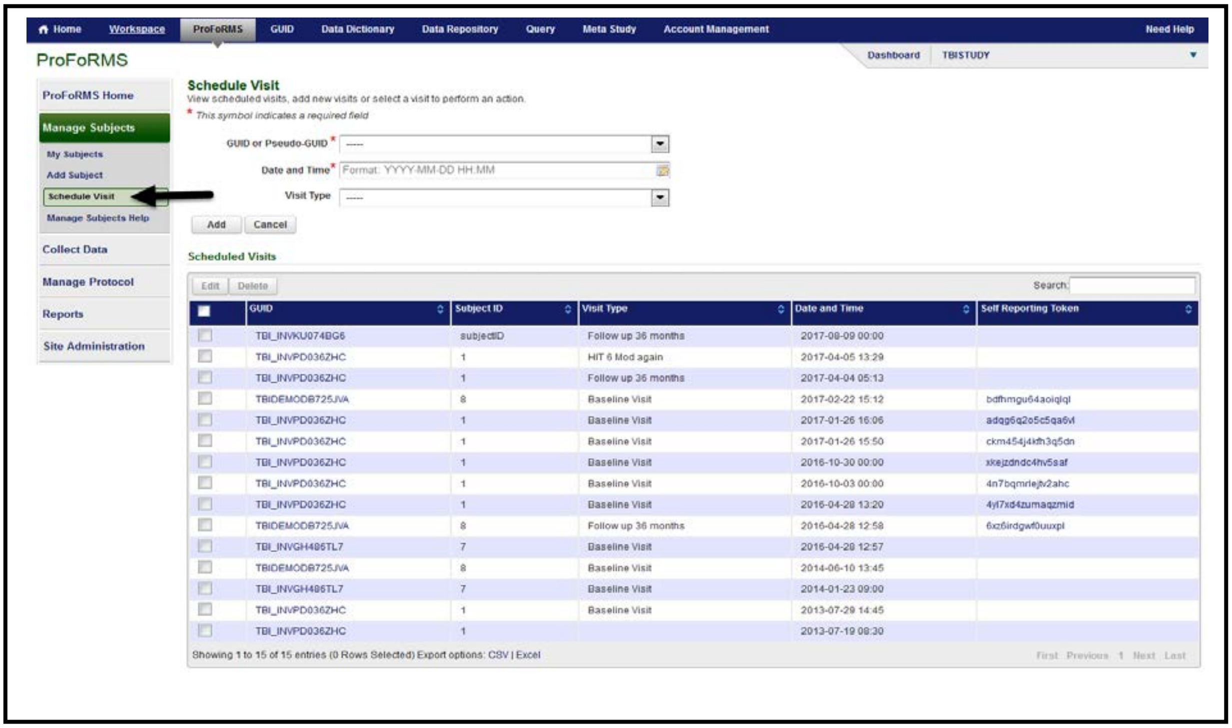
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



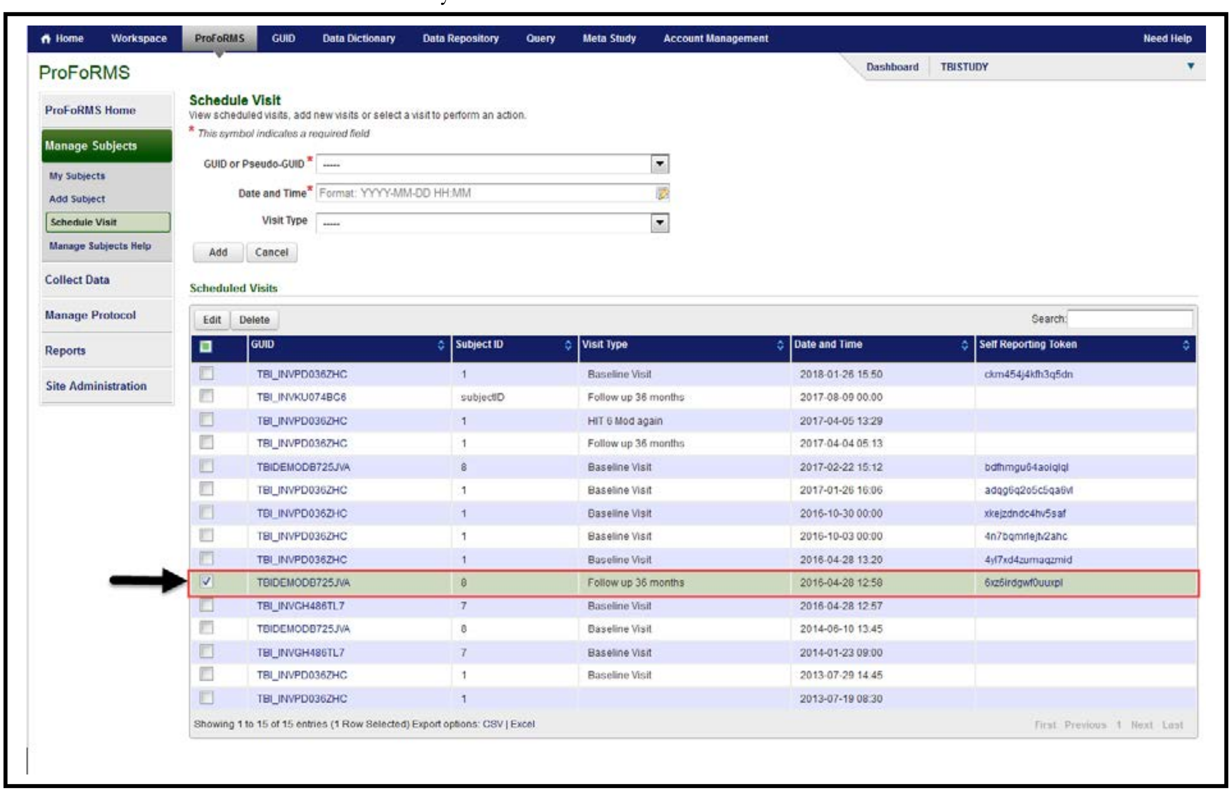
4. **My Subjects** page appears with in a list that can be sorted by clicking on the arrows on any field using the symbol.



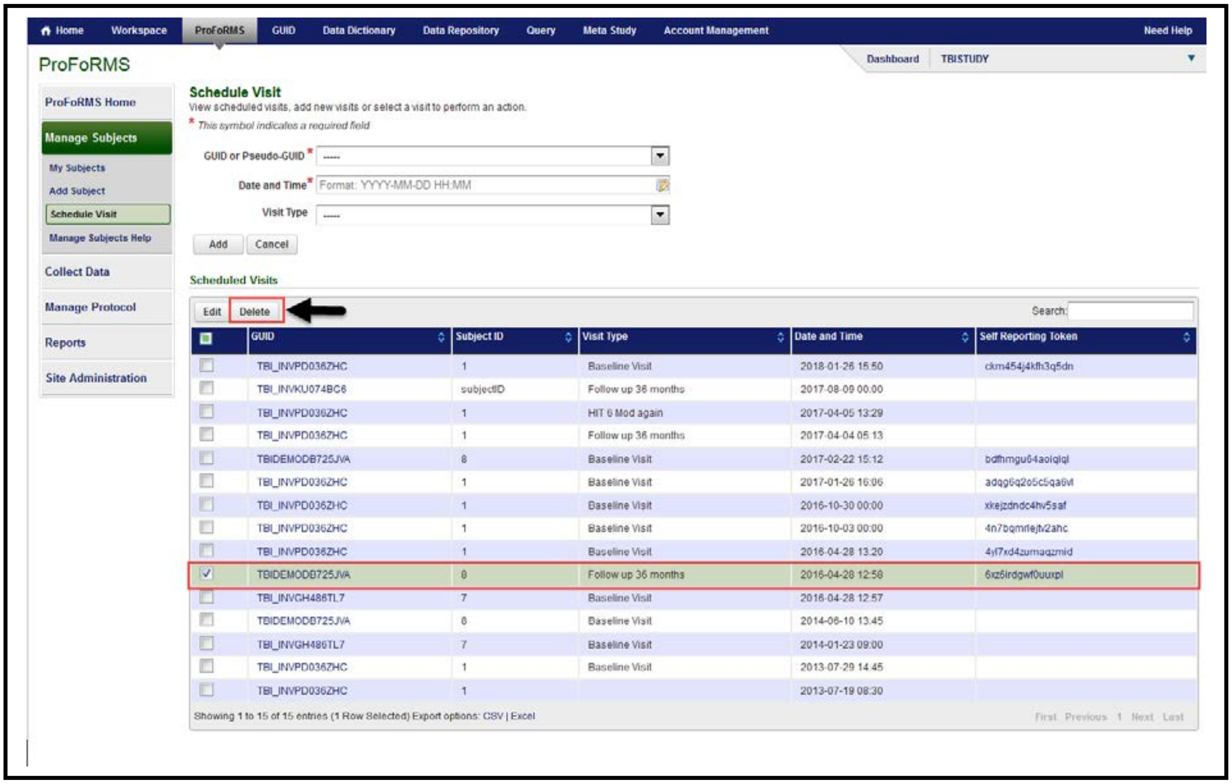
5. Click the **Schedule Visit** tab on the left-side tool bar.



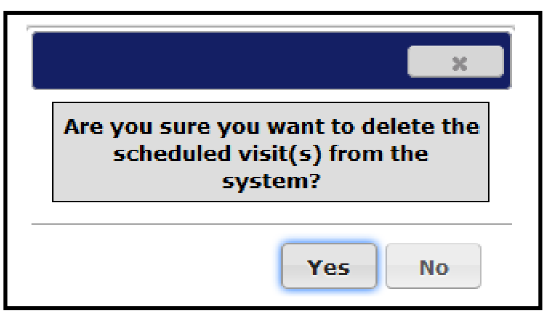
6. The **Schedule Visit** page appears from where you can ***Delete*** a scheduled visit. Select the **Check-box** next to a visit you would like to delete.



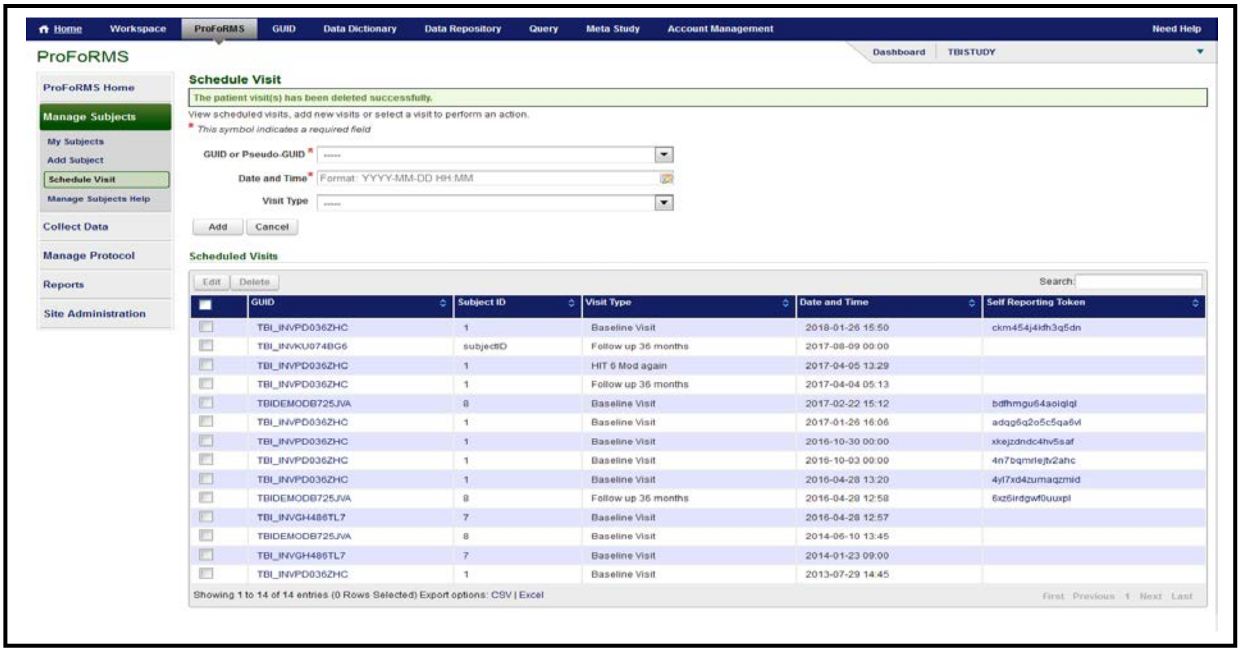
7. Click the **Delete** button.



8. A Pop-up button appears: "*Are you sure you want to delete the scheduled visit(s) from the system?* Click the **Yes** button. Click the **Yes** button to confirm you would want to delete the scheduled visit(s) from the system. Click the **No** button to cancel the update process.



9. The deleted visit will be displayed on the Scheduled Visits list as shown below:

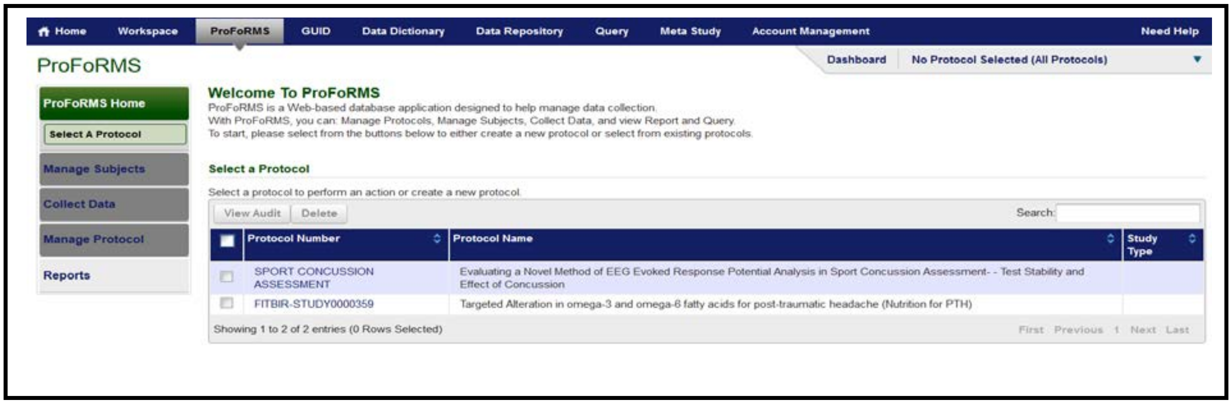


3.6.8 Viewing Scheduled Visits

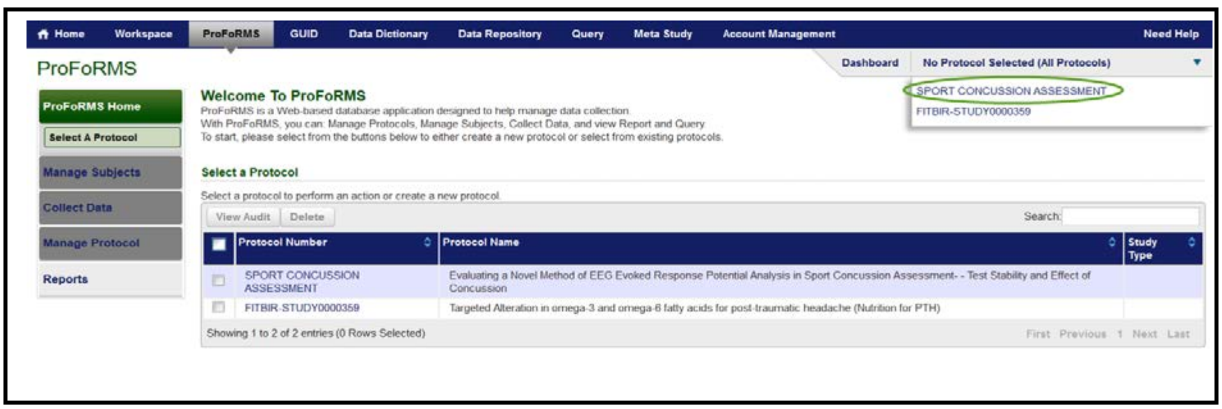
From the **Schedule Visit** page, you can view all your scheduled visits. Sort scheduled visits by **GUID**, **Subject ID**, **Visit Type**, **Date,** and **Time**.

To View All Visits Scheduled on a day: Perform the following actions:

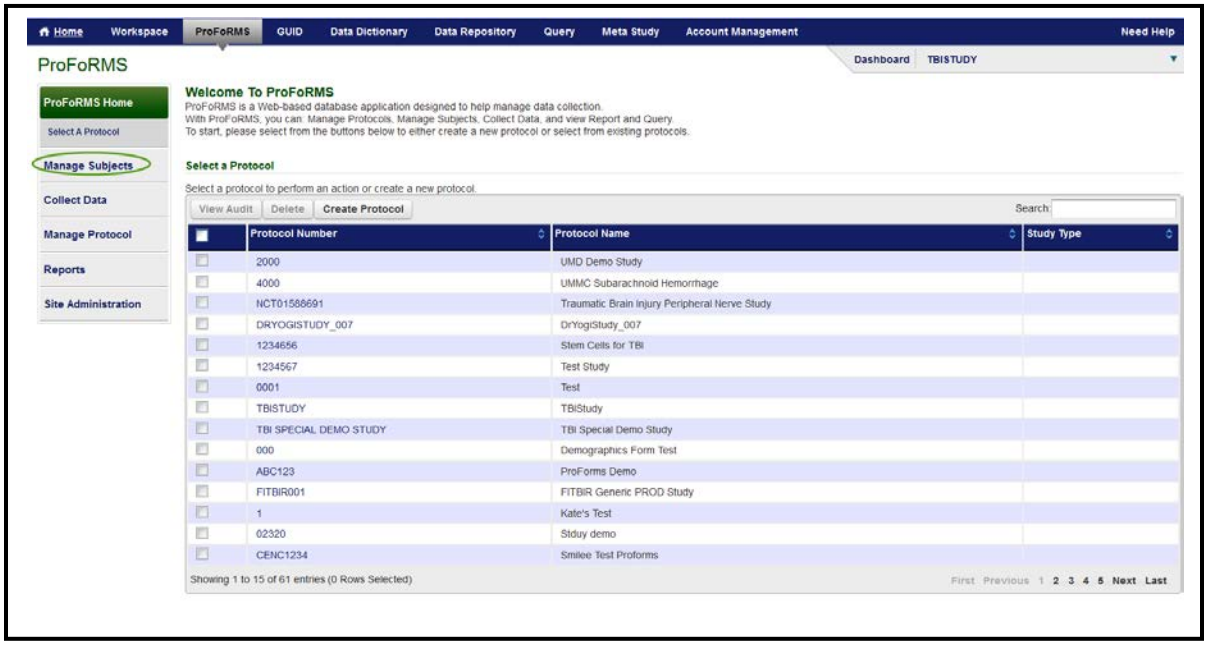
1. Navigate to the **ProFoRMS** module



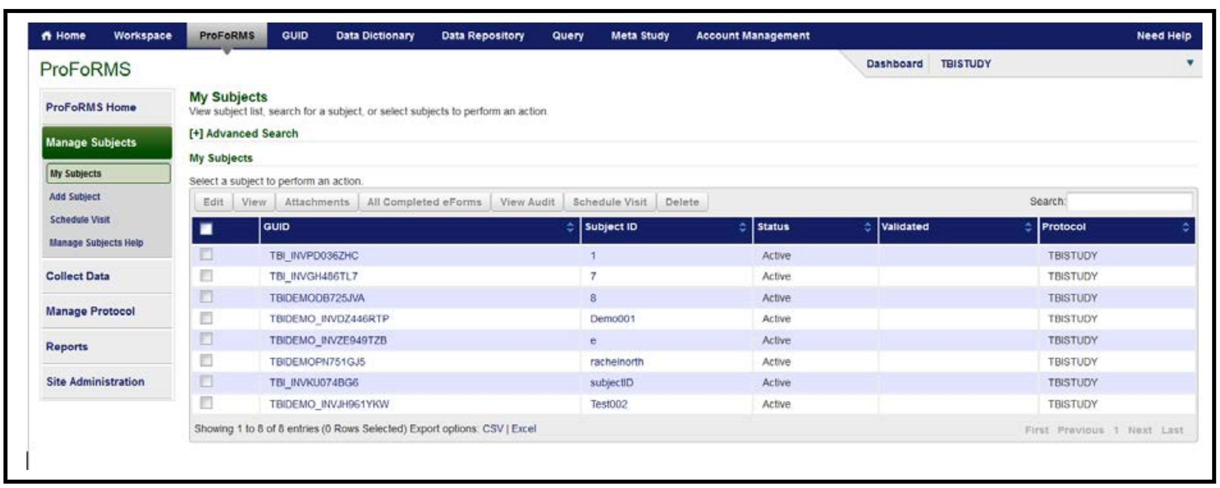
2. Select a **Protocol** by using the drop-down menu located on the top right-hand corner.



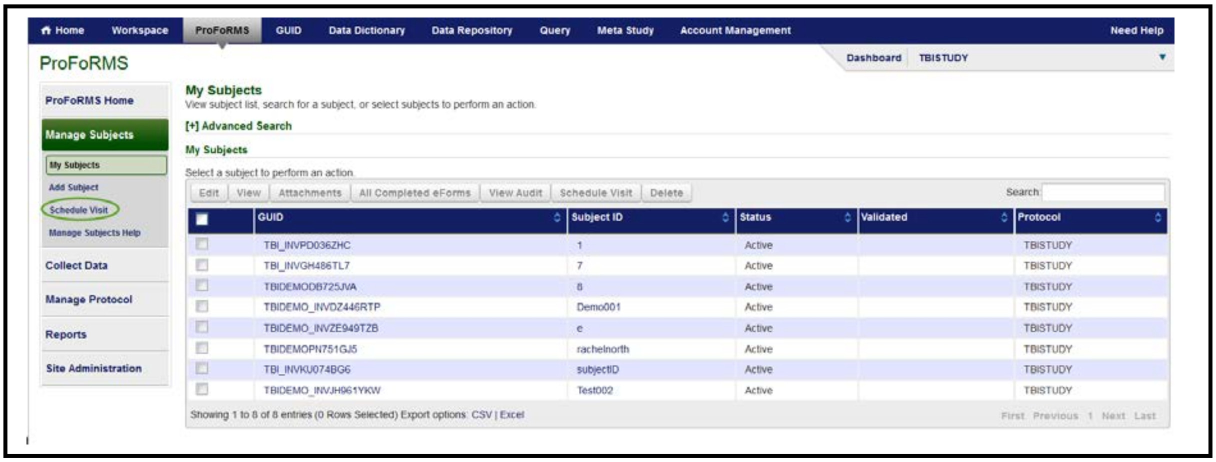
3. The ProFoRMS Dashboard opens. Click the **Manage Subjects** on the left-side tool bar.



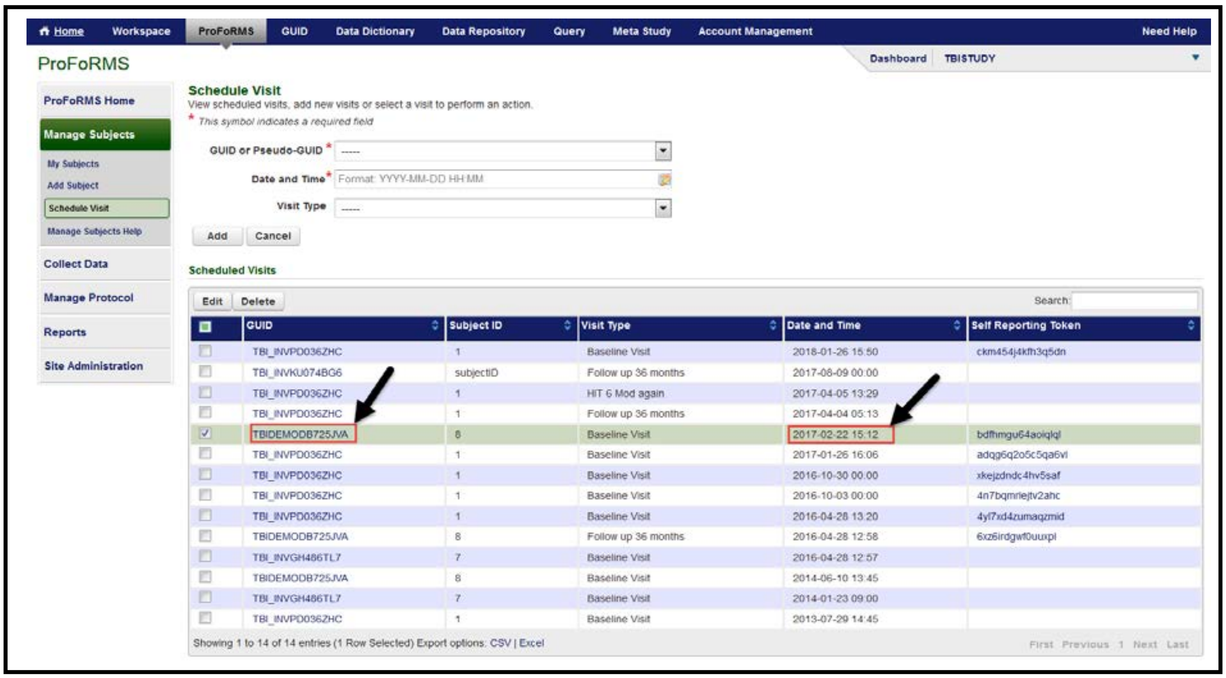
4. **My Subjects** page appears with in a list that can be sorted by clicking on the arrows on any field using the symbol.



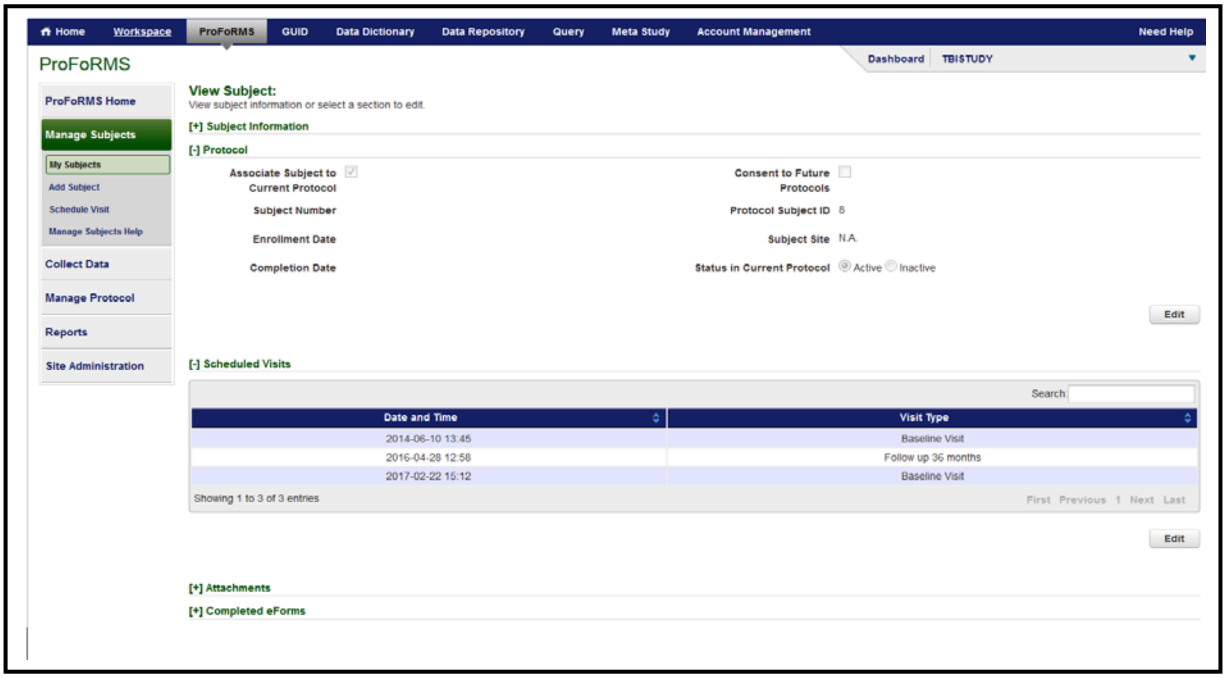
5. Click the **Schedule Visit** tab on the left-side tool bar.



6. Click on the **GUID ID** beside the **Day** you wish to view appointments in the Calendar.



7. The View Subject page appears with Subject Information, Protocol Information, Scheduled Visits information, attached documents, and Completed eForms.



3.7 Collect Data

This feature allows researchers to collect data for subjects and/or specific electronic forms to add new data or modify previously collected data entries, to view and resolve data discrepancies if double entry is specified, perform quality assurance of collected data and monitor subject safety. The module has a functionality that assures that changes are tracked in the system and can be viewed in **Audit Logs**.

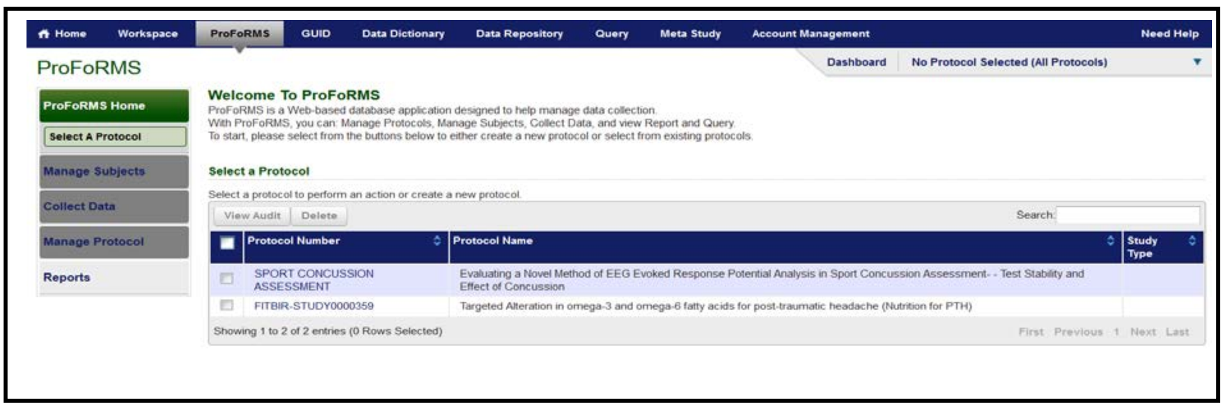
Clinical data may be captured electronically at its source, or in paper form and later transcribed into the system. There are two options for collecting data in ProFORMS:

1. Real-time data entry method; and
2. Pen and paper method, which is then transcribed into ProFoRMS at a later date.

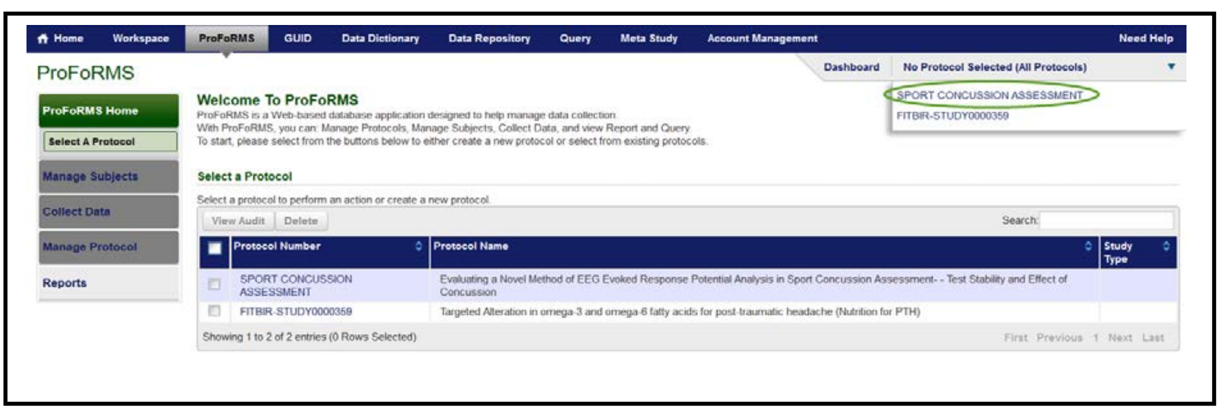
3.7.1 Data Collection (by Subject)

To start Data Collection: Perform the following actions:

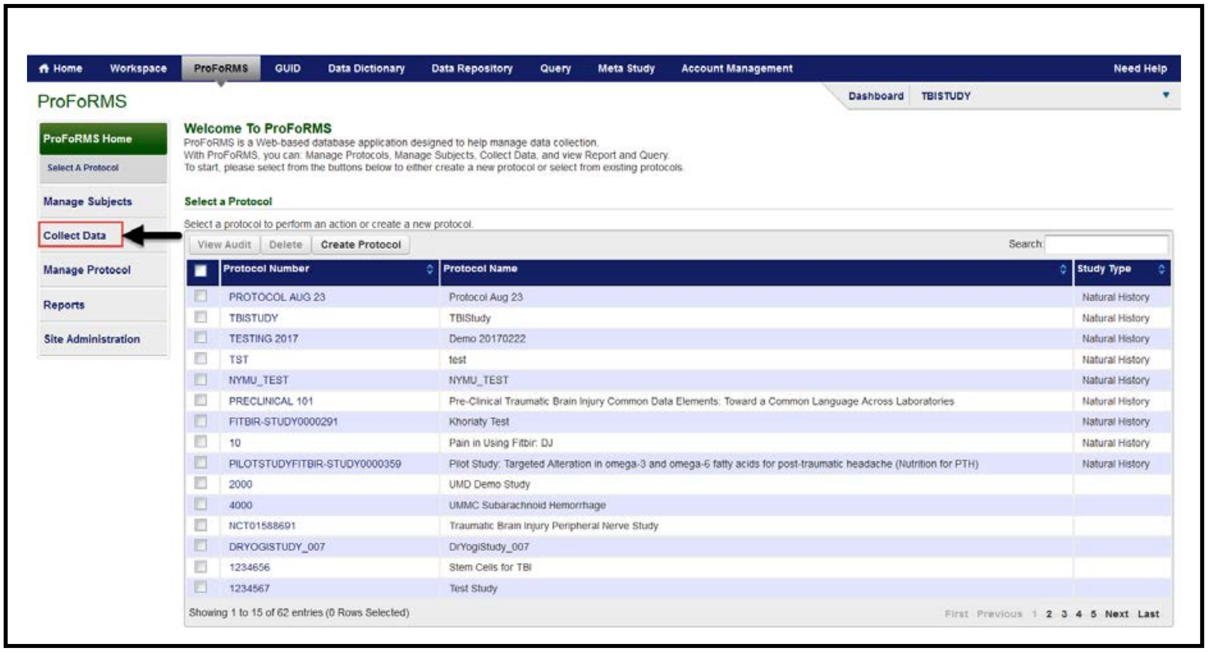
1. Navigate to the **ProFoRMS** module



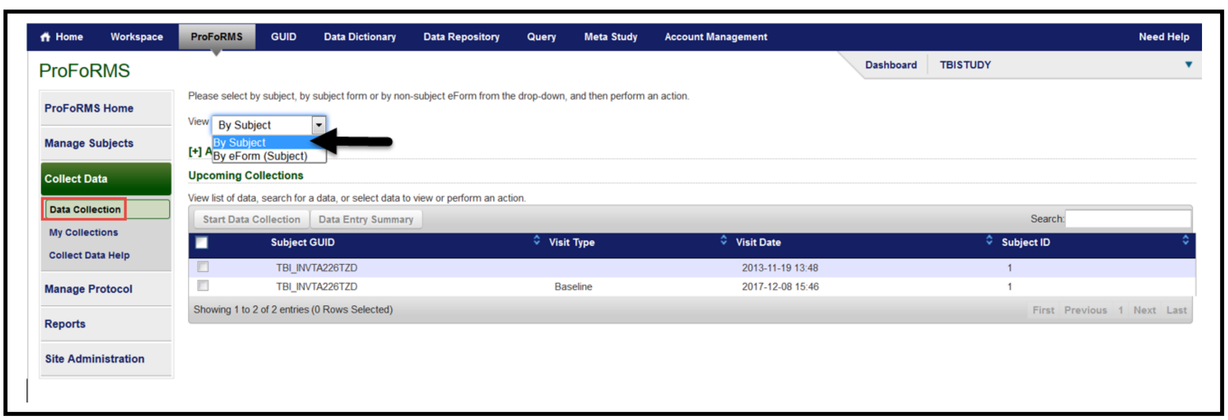
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



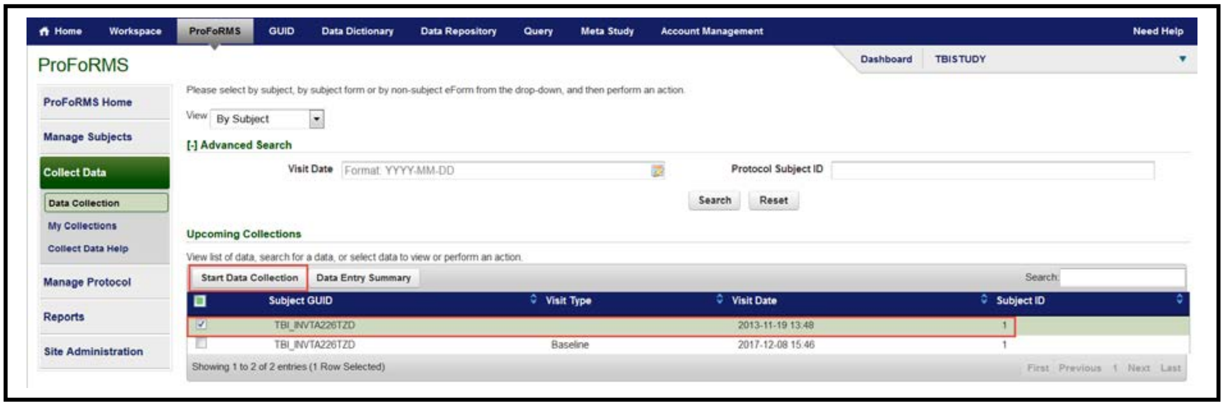
3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



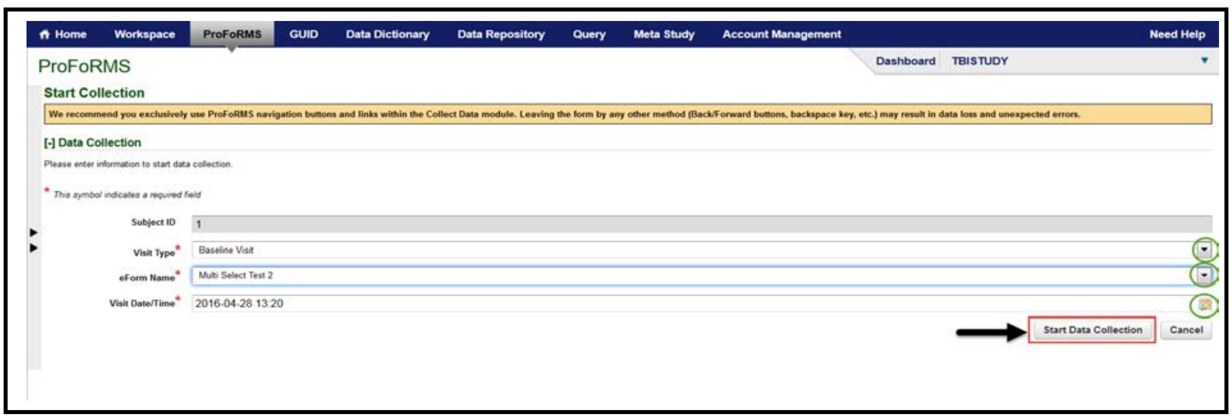
4. Click the **Collect Data** on the left-side tool bar. Select by subject, by subject form or by non-subject eForm from the drop-down, and select the desired option: View – (By Subject or By eForm (Subject). The Data Collection eForms page opens with the list of **Upcoming Collections** when **View** by **Subject** is selected. Depending on the view you selected, the table will display either the list of subjects, or the list of forms.



5. To start data collection**, Select the Check-box beside the Subject GUID, and** Press the **Start Data Collection** button**. Note:** We recommend you exclusively use ProFoRMS navigation buttons and links within the Collect Data module. Leaving the form by any other method (Back/Forward buttons, backspace key, etc.) may result in data loss and unexpected errors.

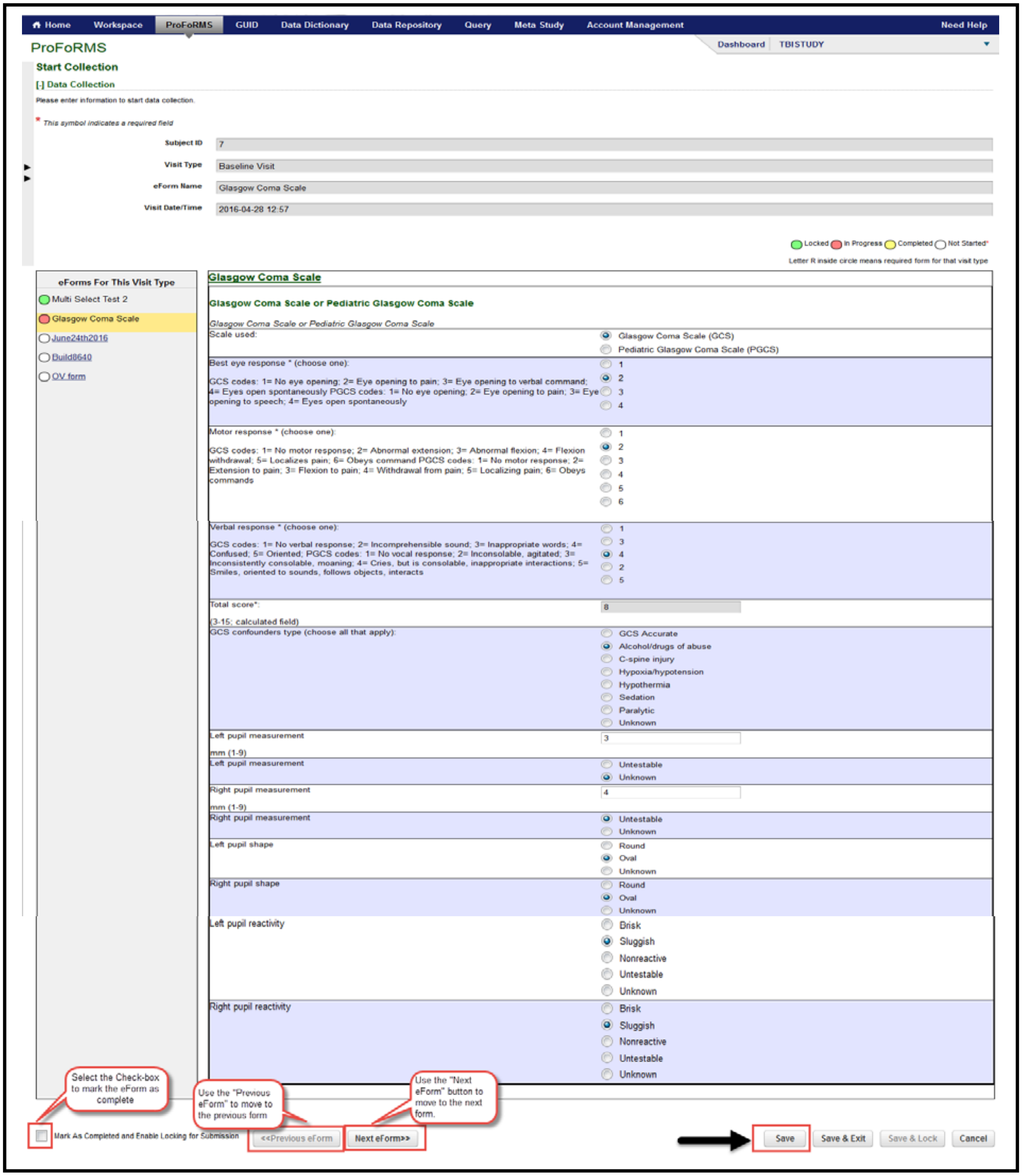


6. Enter the required information (Subject ID, Visit Type, eForm Name, Visit Date/Time) and Click the **Start Data Collection** button. **NOTE**: Visit Type and Visit Data/Time is auto-populated, but can be edited.

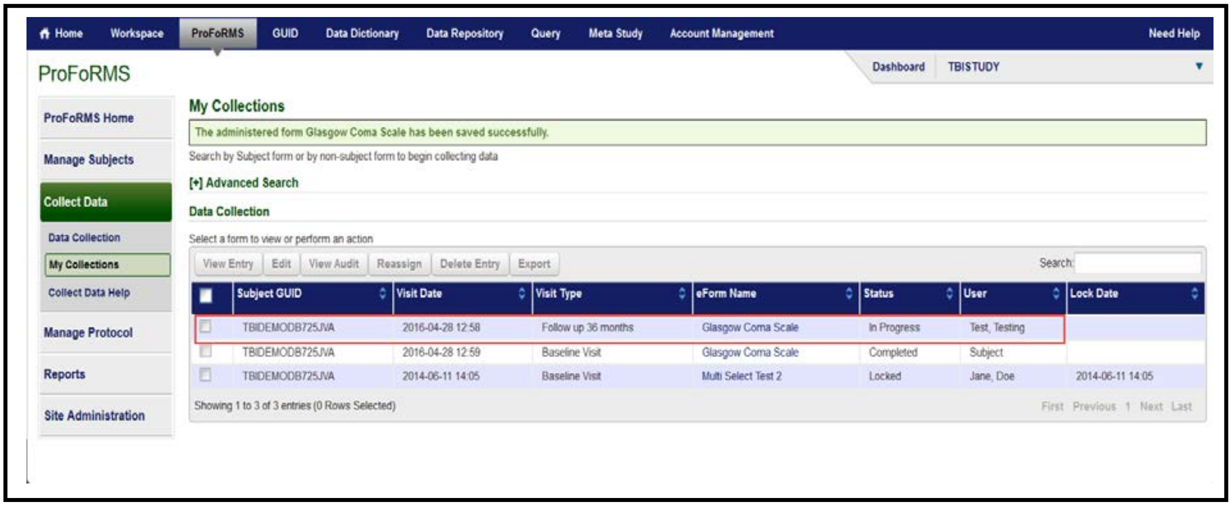


7. Enter the subject information, and Protocol information and other fields to add a subject. Mandatory fields are marked with asterisk *. Click the **Save** button. **Note:** Visit Type and Visit Date/Time is auto-populated, but it can be edited. Click the **Save** button. Once an eform has been saved, you will be directed to My Collections page which provides a table of the eforms and their statuses.

   NOTE: There are certain fields that are auto-populated on the form beyond Visit Type and Visit Date/Time. This can be configured when creating/editing a visit type under the Protocol Information. Mandatory fields do not have to be completed to save a collection. The save button will save the user's progress automatically regardless of its current completion status.



8. A visit will be considered “Complete” when all required forms for a particular visit type are labeled “In Progress”. The collection data is saved in **My Collections** page with a confirmation of the changes as shown below:



ICON KEY

Notes

Important Information

Things to Note:

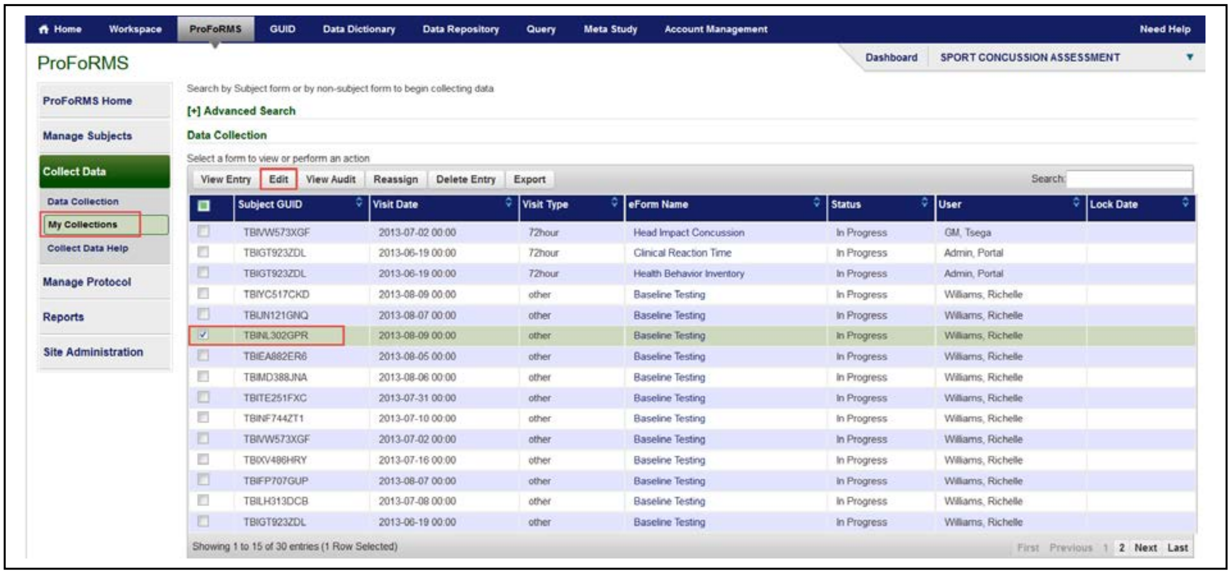
- To reset the questions on the eform, double-click on the **Radio** buttons
- To save the eform, use the **Save** button at the bottom of the eform
- To cancel the data collection process, simply click on the **Cancel** button
- The system auto-saves the eform every **8 minutes**
- All Required fields are marked by **red asterisks**
- Certain questions are greyed-out by **Skip logic**
- Auto-calculated fields that appear in several forms. Answers will appear if you click on them, but it is **NOT** necessary to save the eform.
- Green sections are collapsible. User can expand/hide to read further instructions or view scoring sections.
- To leave the form and complete it at a later date and time, use the "**Save & Exit**" button

3.7.2 Locking the eForm

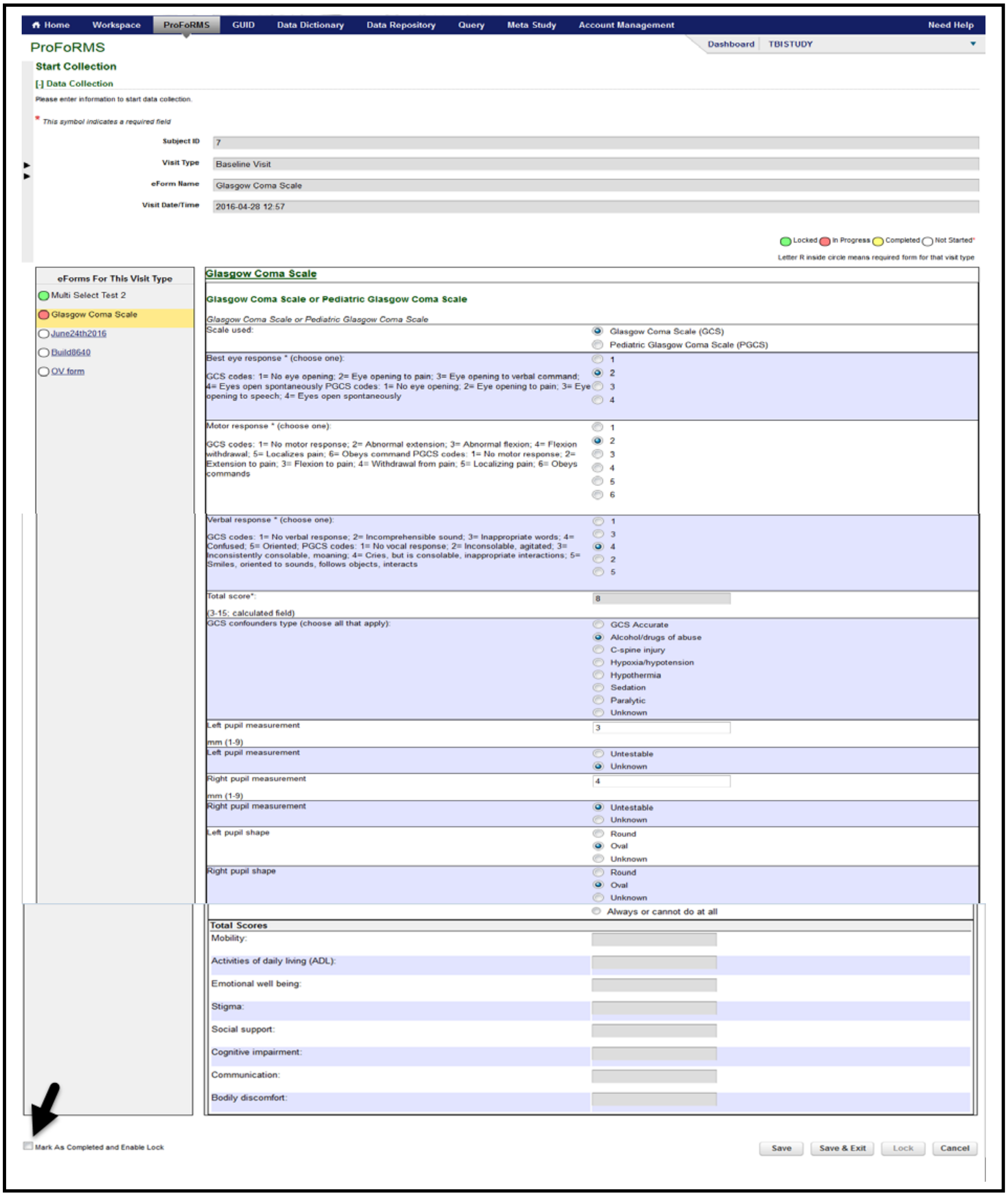
After entering data in the form and click the Save button, you will be taken to the My Collections view. Forms will continue to show as "In Progress" until they are locked. Data should not be locked untull reviewed and ready for final submission.

To lock your form: Perform the following actions:

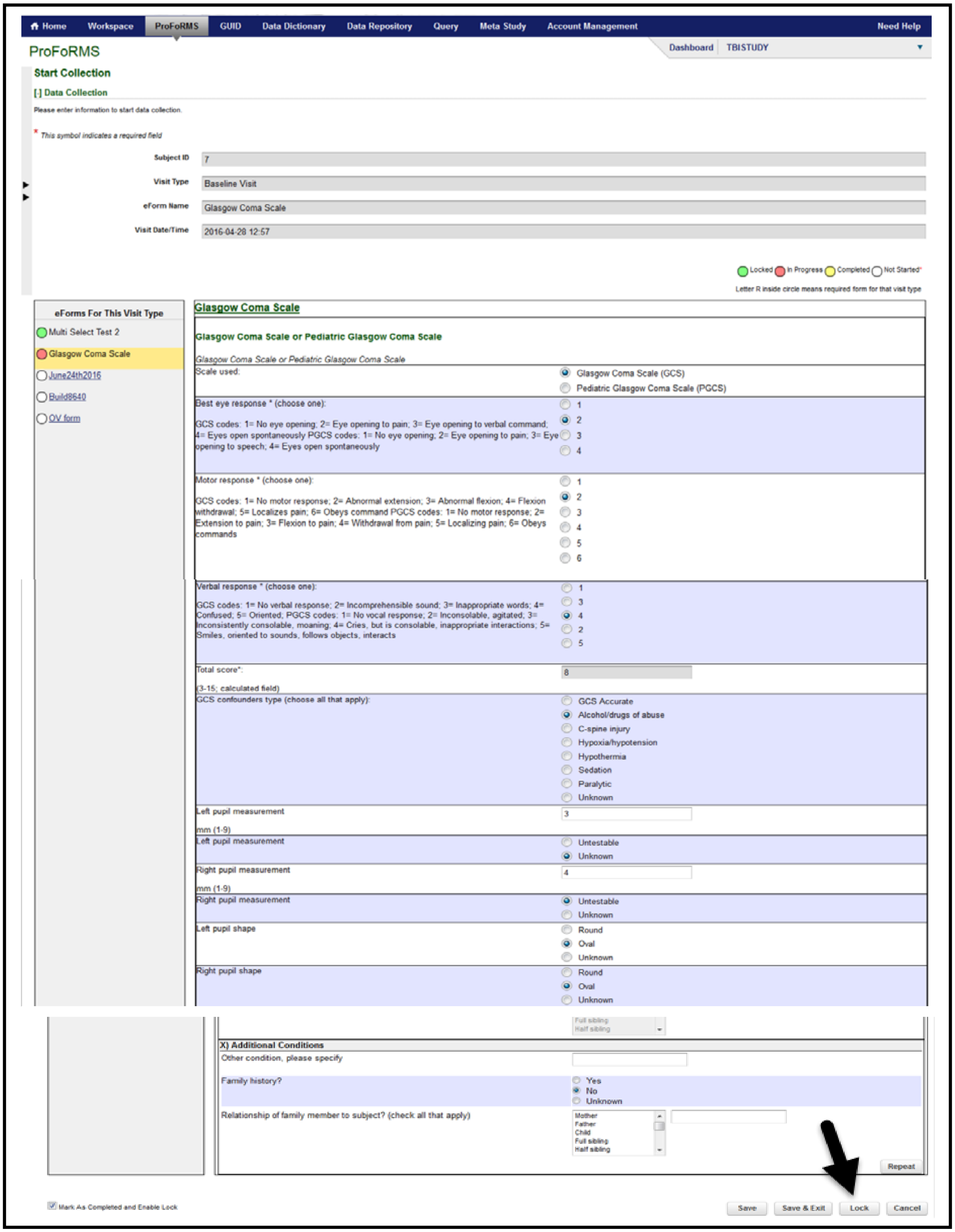
1. When the data has been reviewed and is ready to be locked; select the GUID and form you wish to lock from the "My Collections" page to the **ProFoRMS** module



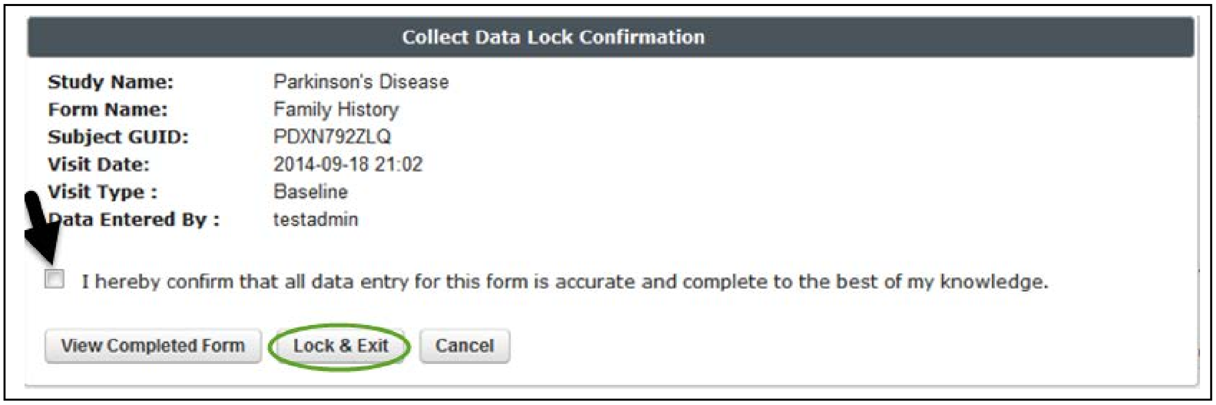
2. Once all of the required questions have been completed, click on the checkbox, "**Mark as Complete and Enable Lock".** If the e-signature is enabled in the protocol information section, then a pop-up will display asking for the user's electronic signature by inputting their password.



3. Once a form as been marked as completed, three things will happen: (1) The "Save & Lock" button will be enabled; (2) The system validation will run (3) An audit trial will start if a user changes their response to an answer. If the form failed you will be notified with a list of the errors and why, along with a link to the question that failed the validation. Once all the errors have been resolved, the user will be able to "save & lock" the form.



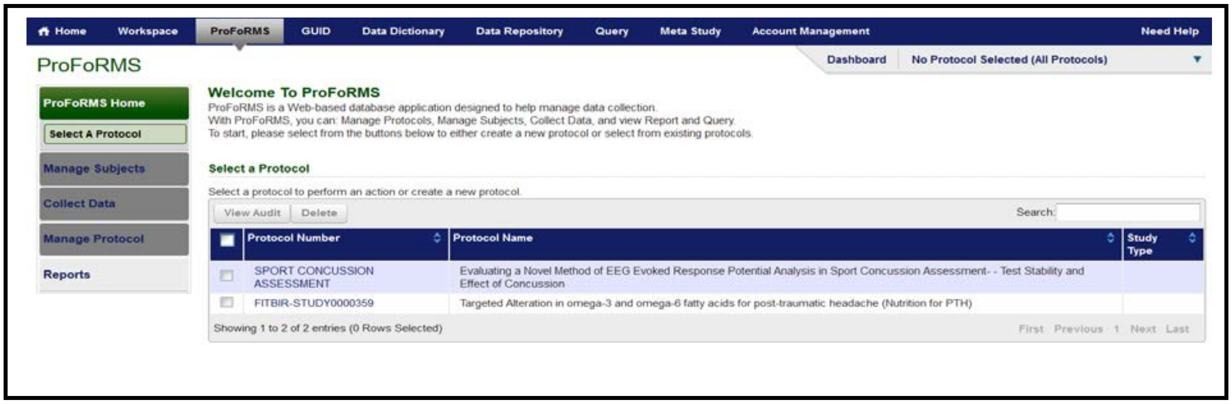
4. Once the form is locked, a "**Collection Data Lock Confirmation**" pop-up window will appear to validate if all information is complete. Select the check-box and Click the **Lock &** Exit button.



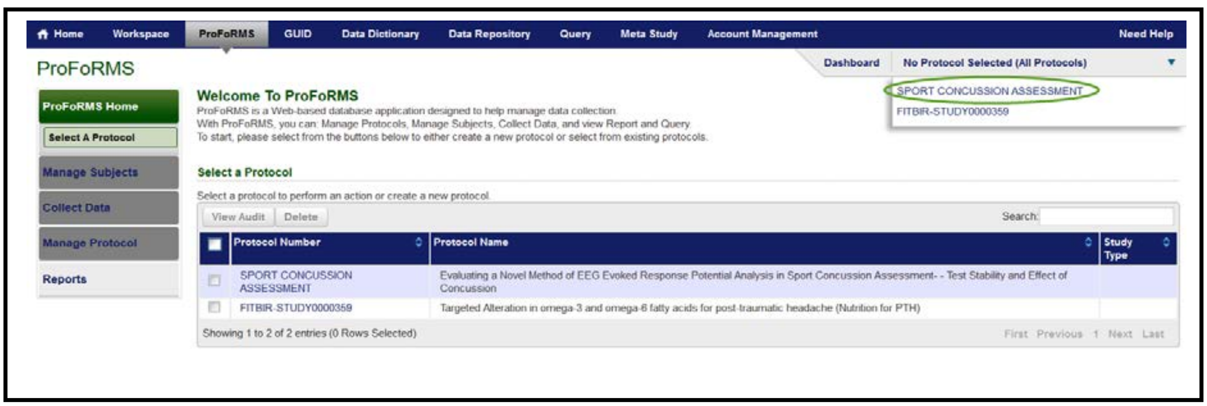
3.7.3 Viewing Data Collection eForms

To view Data Collection eForms: Perform the following actions:

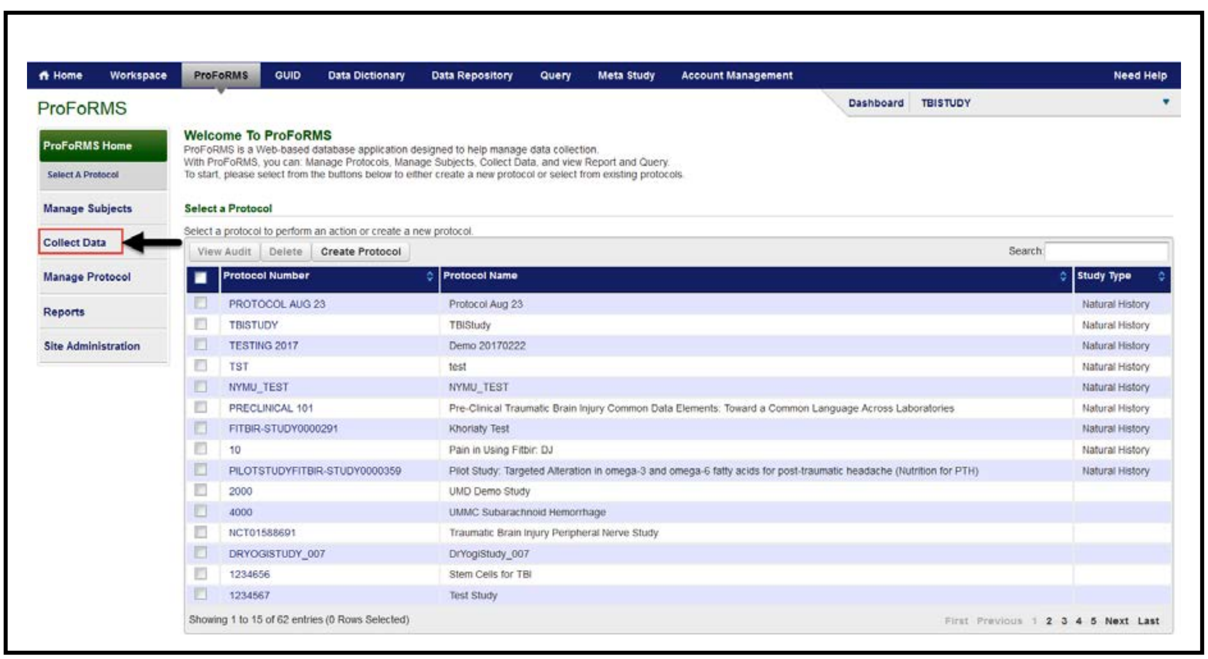
1. Navigate to the **ProFoRMS** module



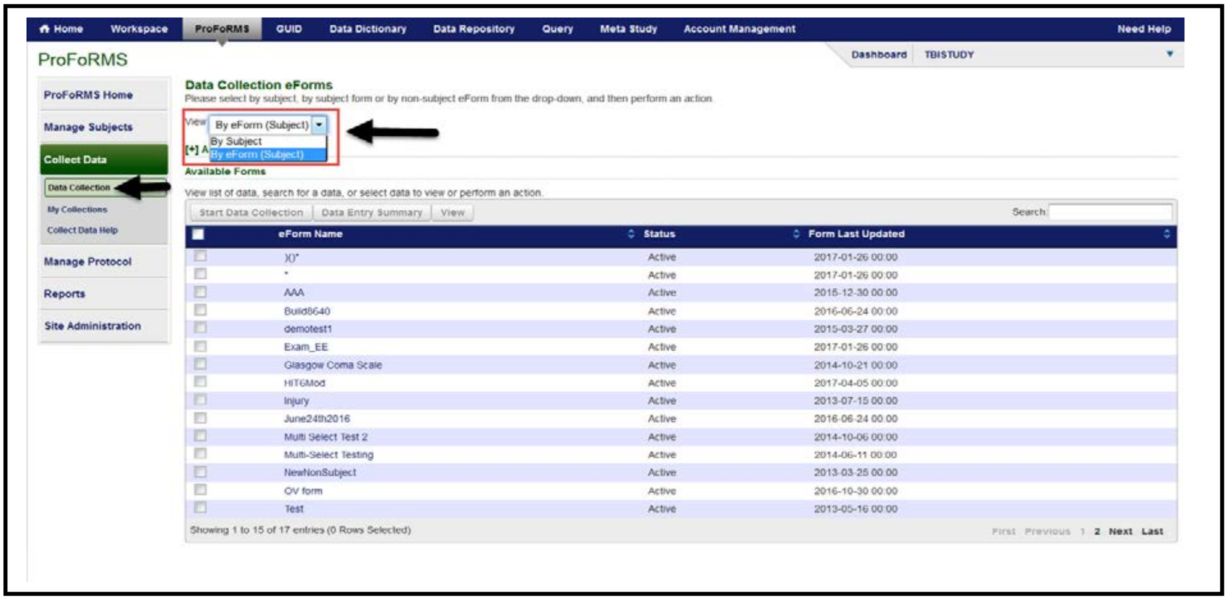
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



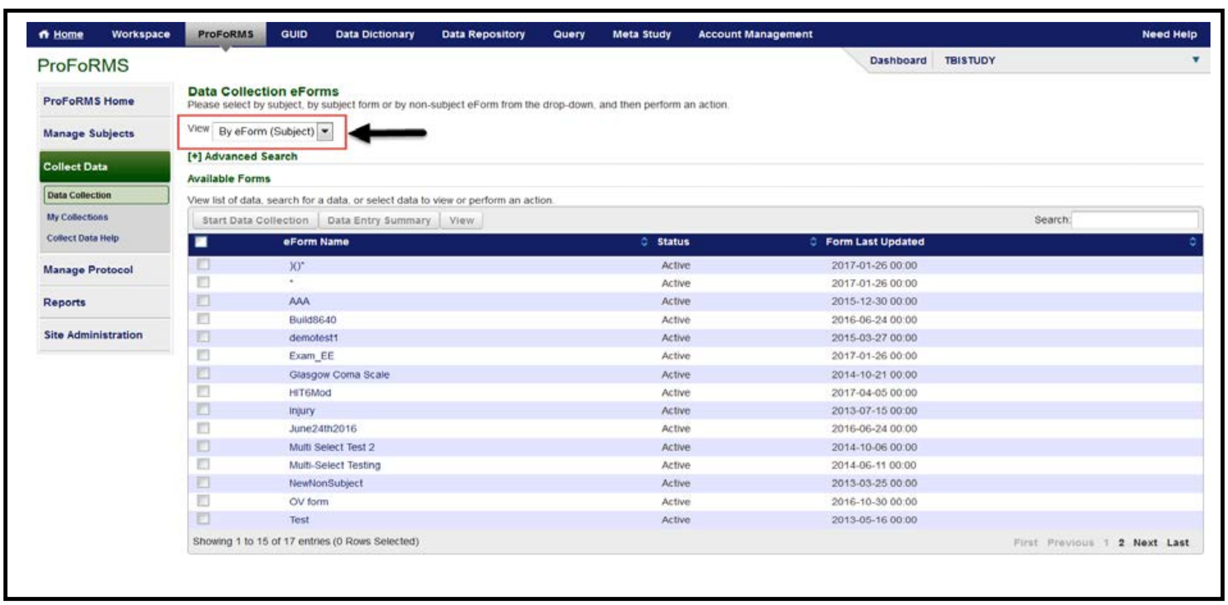
3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



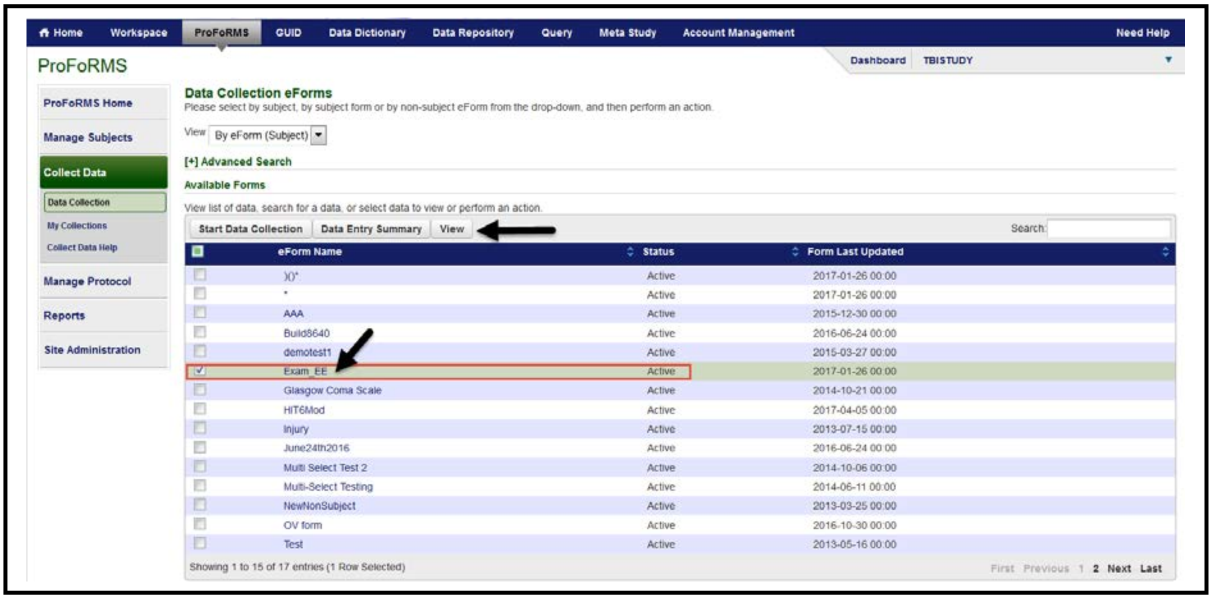
4. Click the **Data Collect** on the left-side tool bar. Select by subject, by subject form or by non-subject eForm from the drop-down, and select the desired option: View – (By Subject or By eForm (Subject). The Data Collection eForms page opens with the list of **Upcoming Collections** when **View** by **Subject** is selected. Depending on the view you selected, the table will display either the list of subjects, or the list of forms.



5. The Data Collection eForms page opens with the list of **Available Forms** when **View** by **eForm (**Subject) is selected.



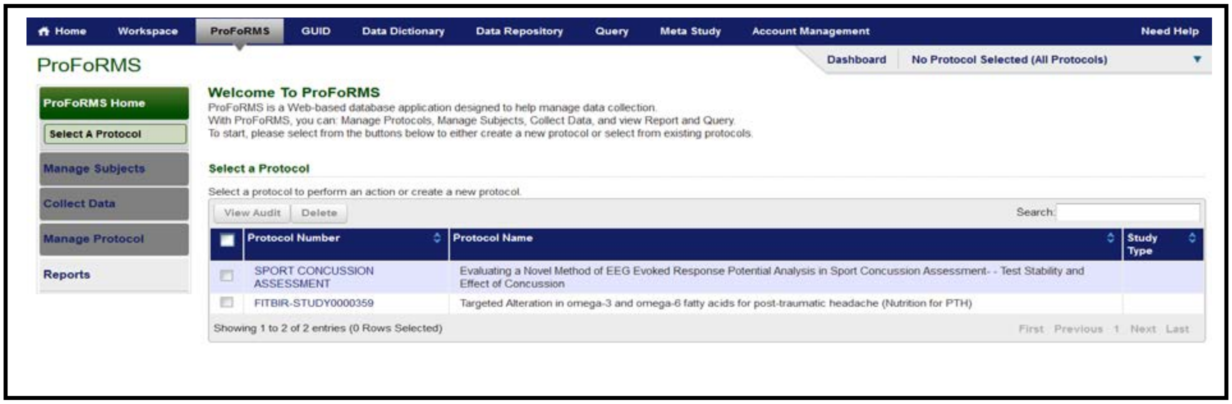
6. Click on the **eForms Name** OR Select the **Check-box** beside the eForm Name and Click the **View** button to open the **eForm** details;



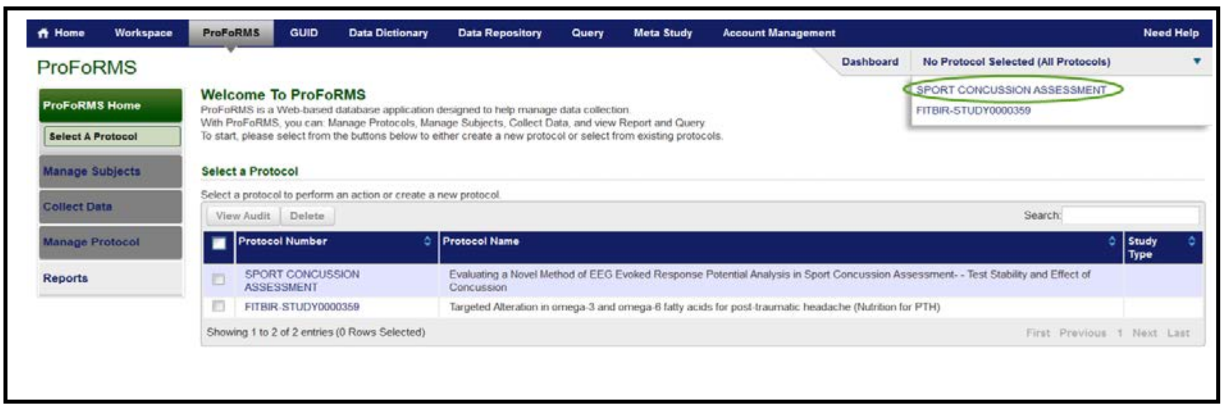
3.7.4 Viewing My Collections

To view data collections: Perform the following actions:

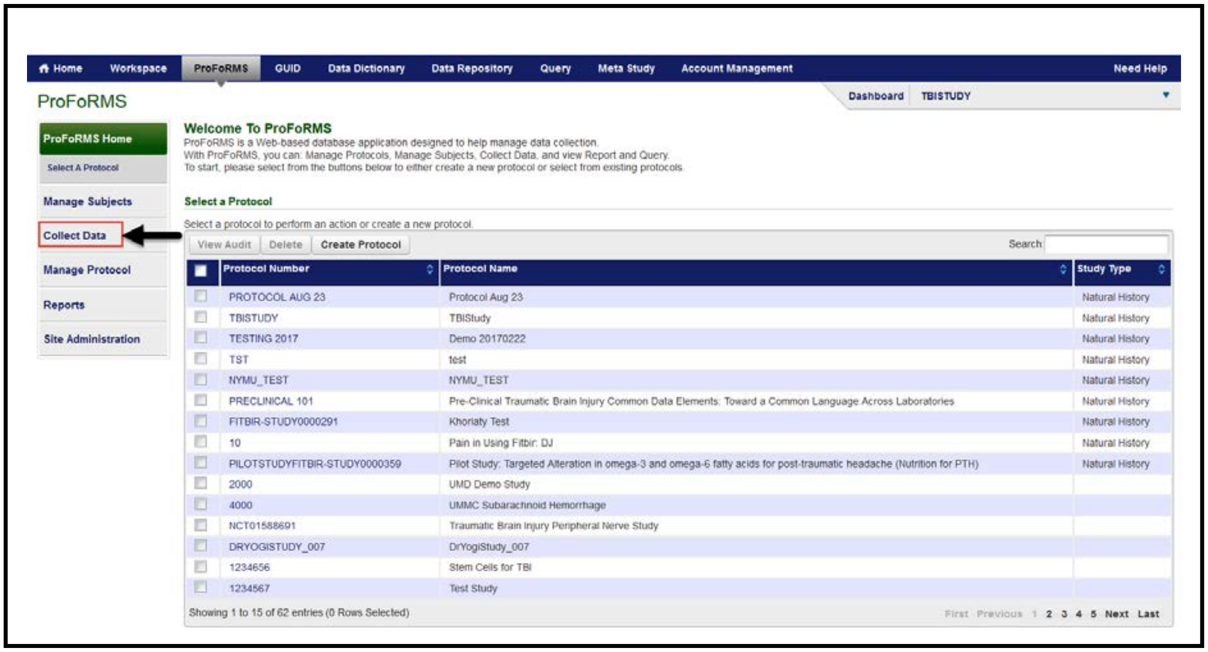
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



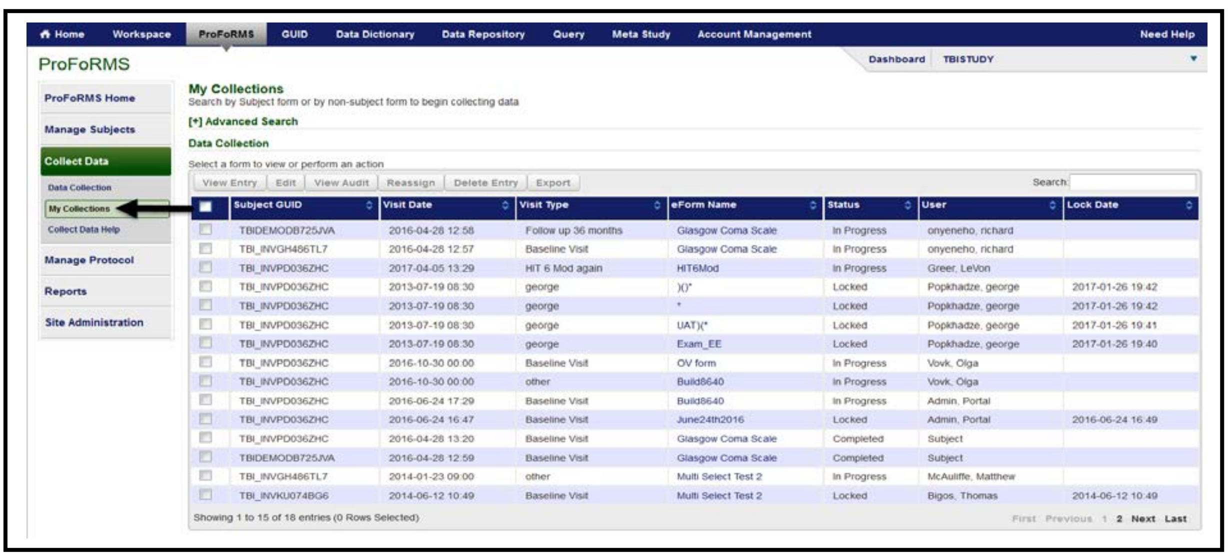
3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, you can perform the following actions: **View Entry**, **Edit**, **View Audit**, **Reassign**, **Delete Entry** and **Export**

Note: Only the Non-Admin owner of collection OR ProFoRMS Admin/global Admin User will be able to edit an eform whose status is "in progress" or "complete". Once the collection has been locked, nonadmin users will no longer be able to edit the eform.

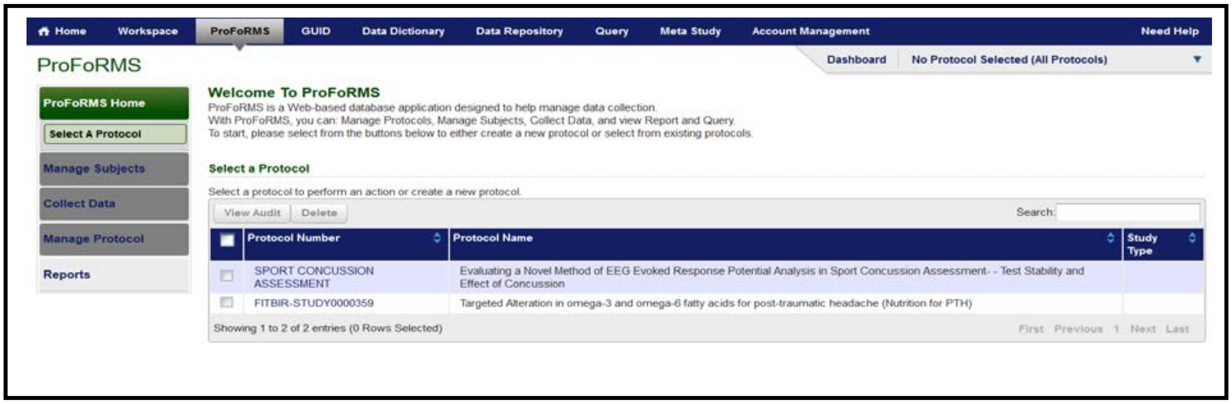
When a user edits a completed form, an audit trail starts for any changed answers.



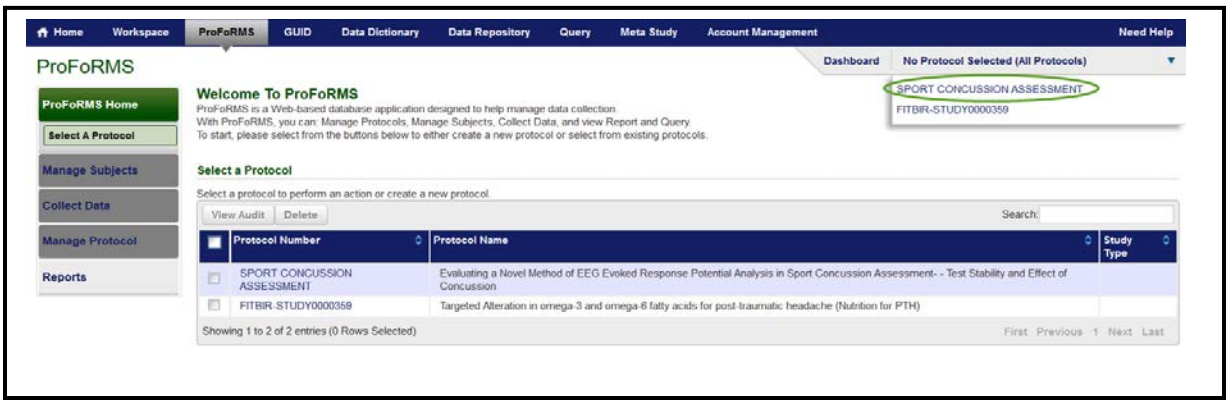
3.7.1 Reassigning Data Collections Entry Form

To reassign data collections entry form: Perform the following actions:

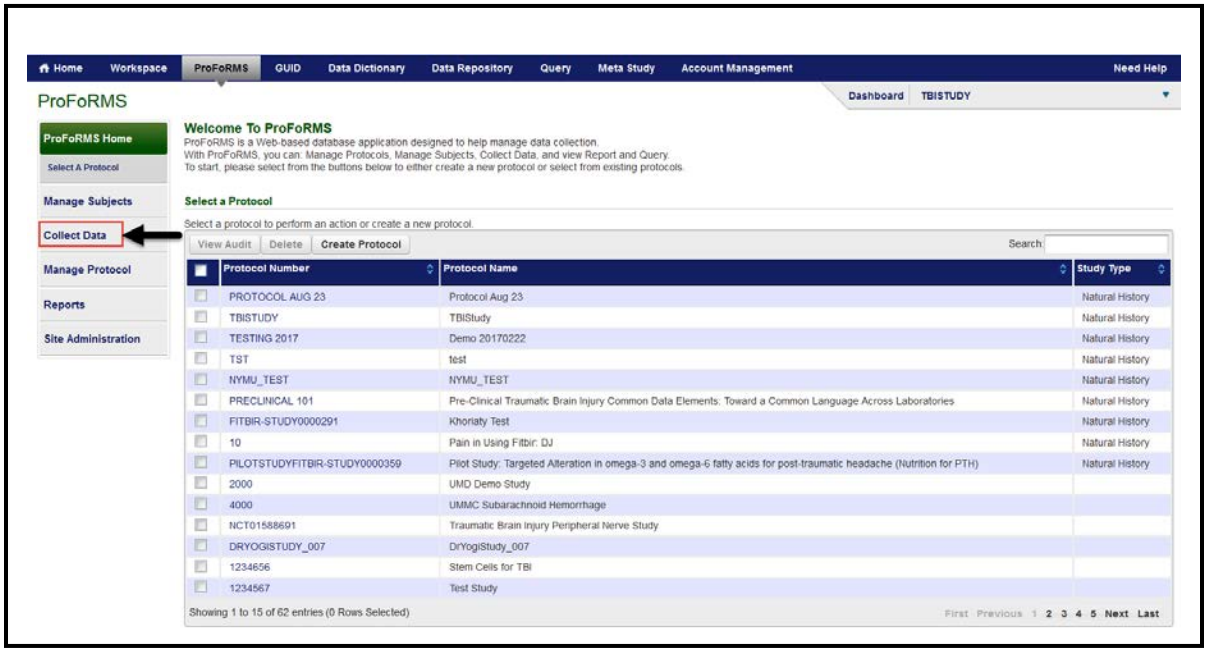
1. Navigate to the **ProFoRMS** module



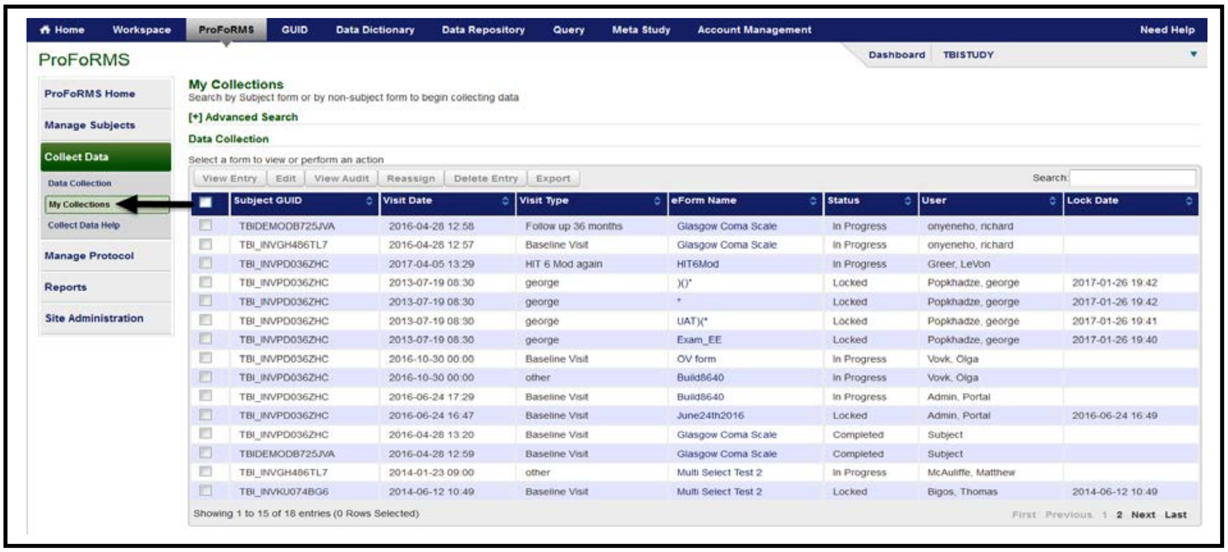
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.

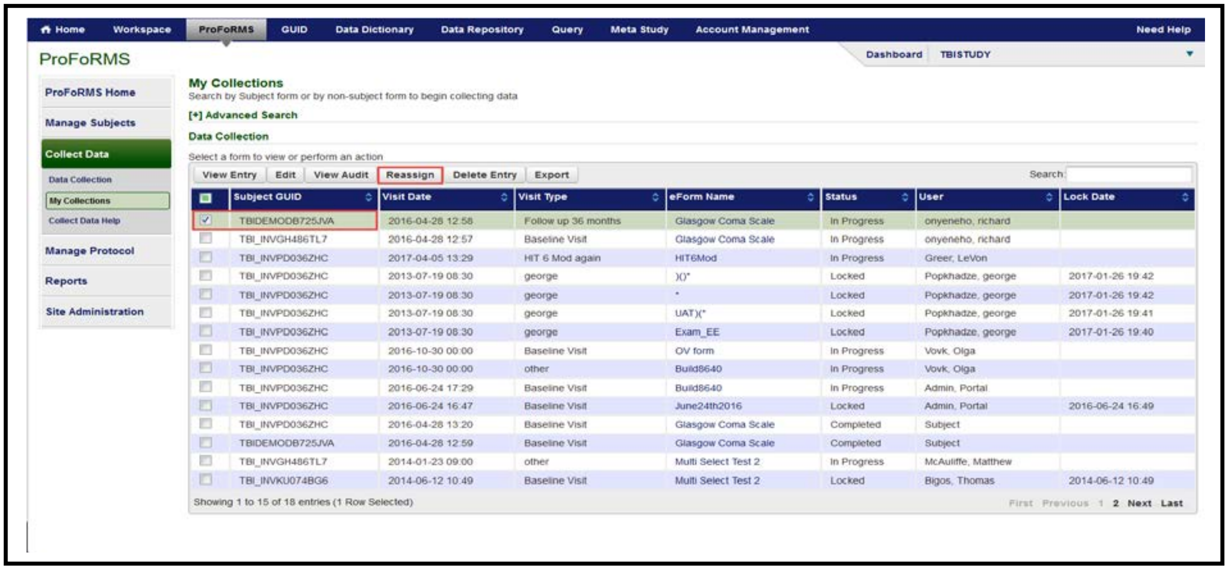


4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, you can perform the following actions: **View Entry**, **Edit**, **View Audit**, **Reassign**, **Delete Entry** and **Export**

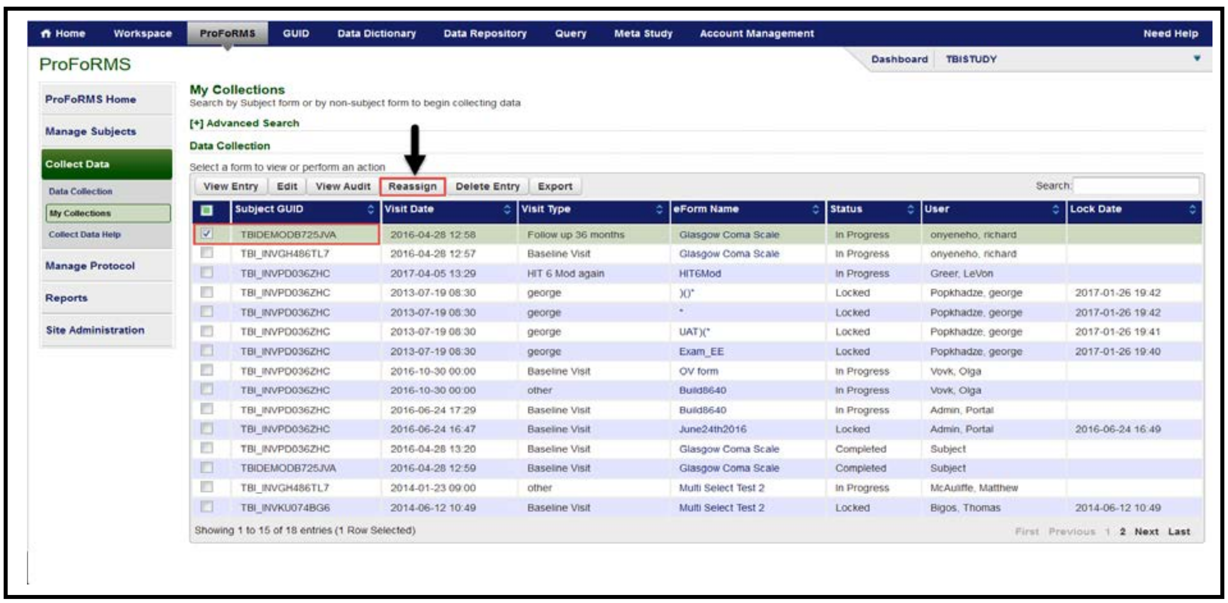


5. Select the Check-box next to the Subject you would like to reassign. **Note**: The ability to assign the form to another user for editing are limited to:
   - *Global Admin Users,*
   - *Non-Admin Users with Primary Investigator (PI) Role,*
   - *Non-Admin Users with Clinical Coordinators Role,*
   - *Non-Admin Users with Study QA Role, and*

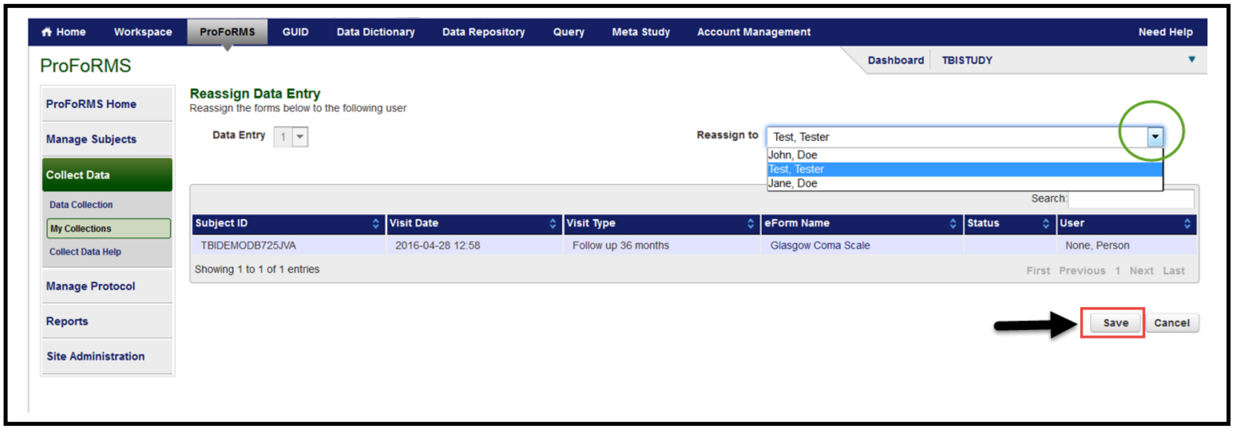
- *Non- Admin Users with a role that has the privileges to Reassign Data Entry.*



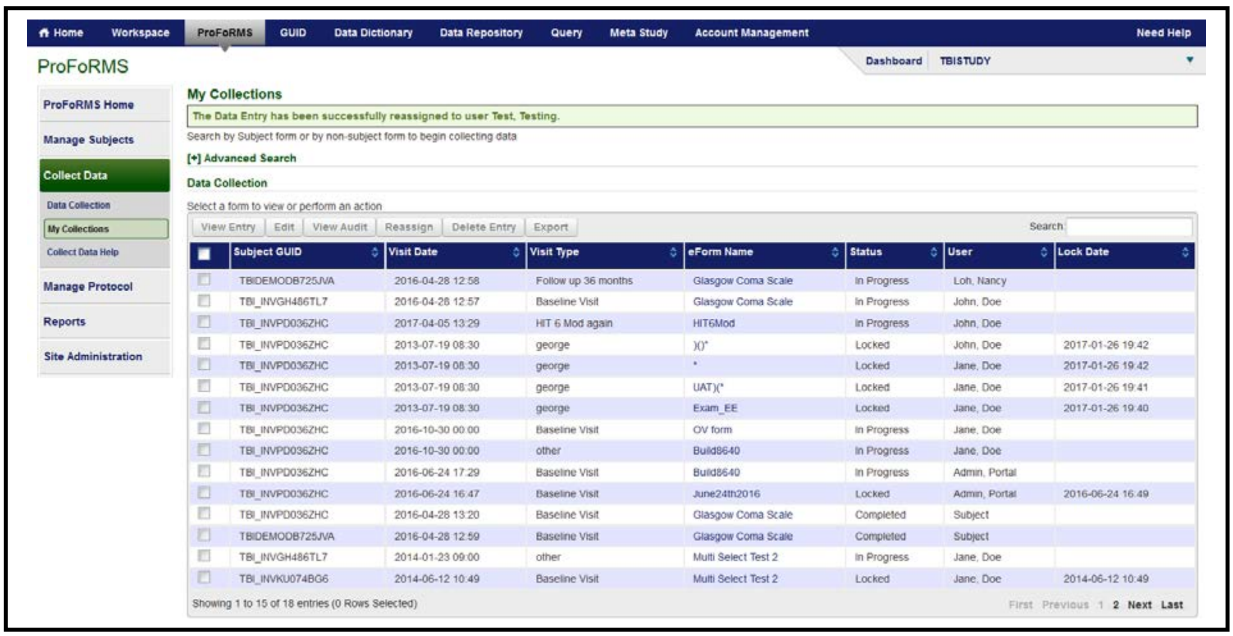
6. Click the **Re-assign** button. The **Reassign Data Entry** page appear.



7. Using the drop-down menu, select the desired user to reassign the form. Click the **Save** button.



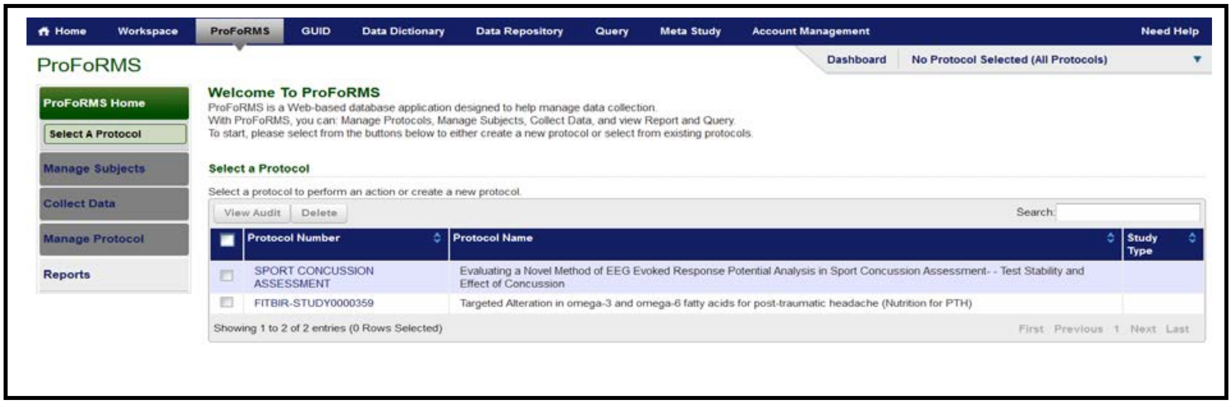
8. The **My Collections** page appears with the reassigned form updated.



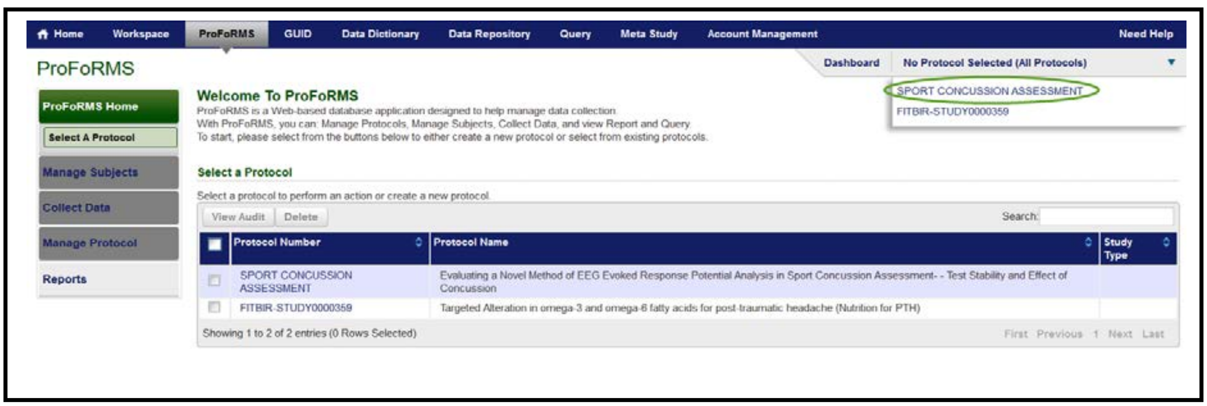
3.7.2 Viewing eForm Information

To view eForm Information: Perform the following actions:

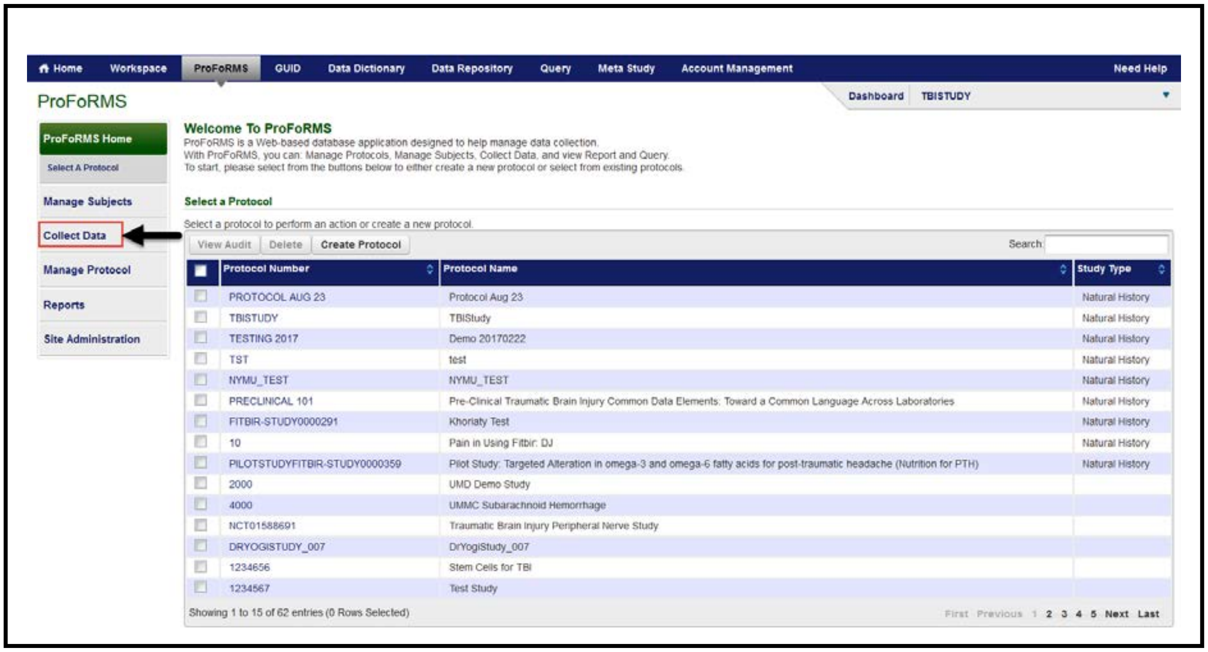
1. Navigate to the **ProFoRMS** module



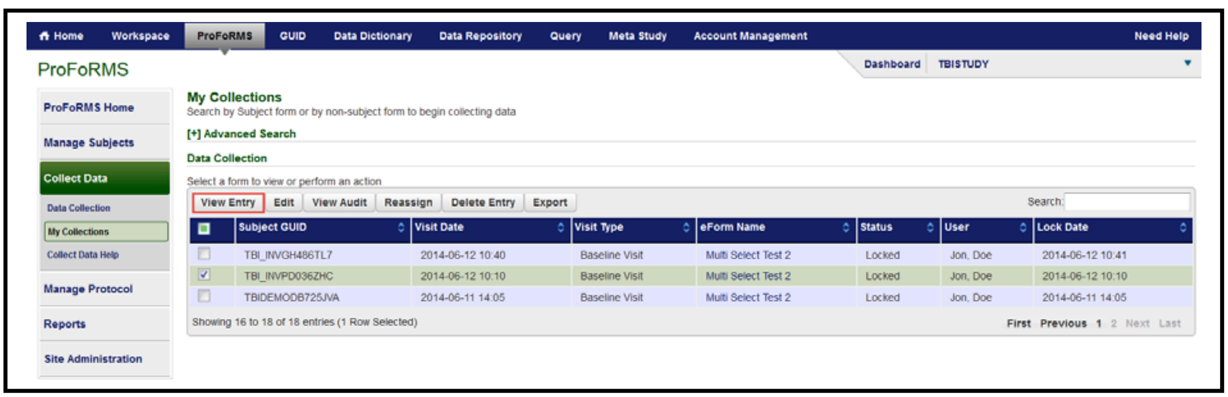
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



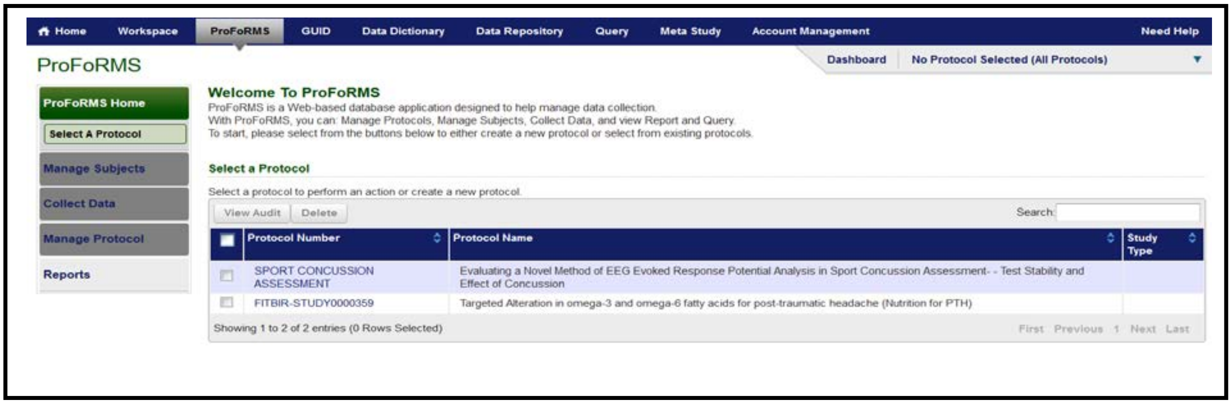
4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, Click the **View Entry** button.



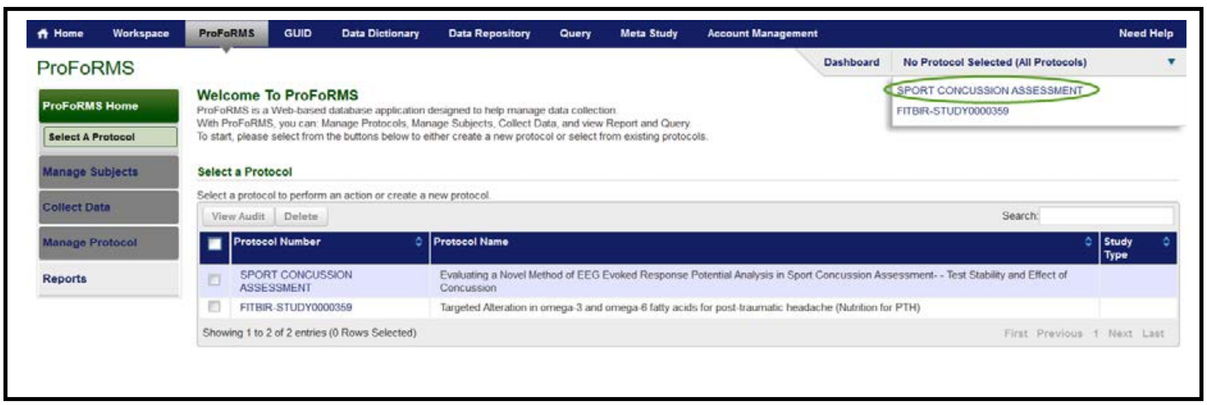
3.7.1 Deleting My Collections

To Delete Data Entry eForm: Perform the following actions:

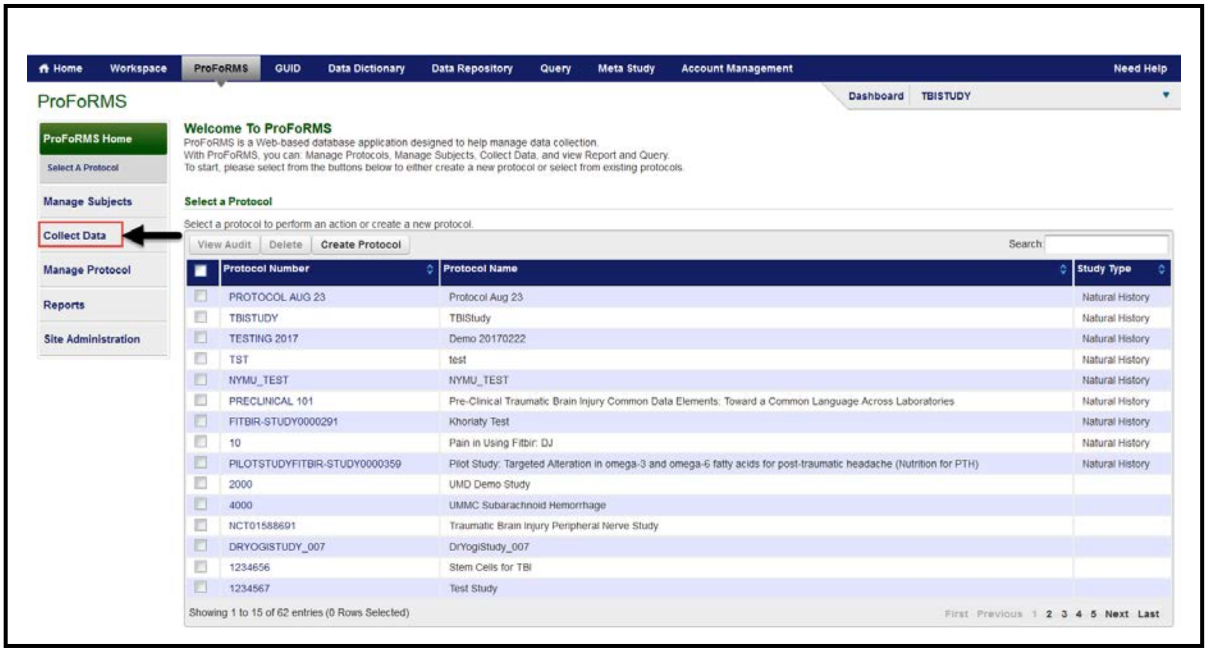
1. Navigate to the **ProFoRMS** module



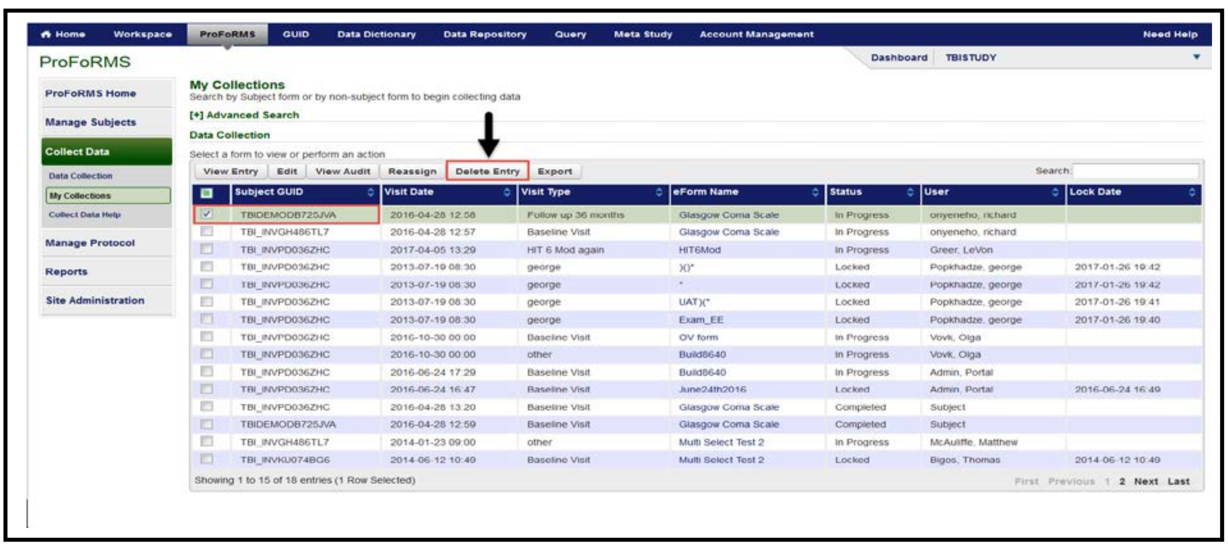
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



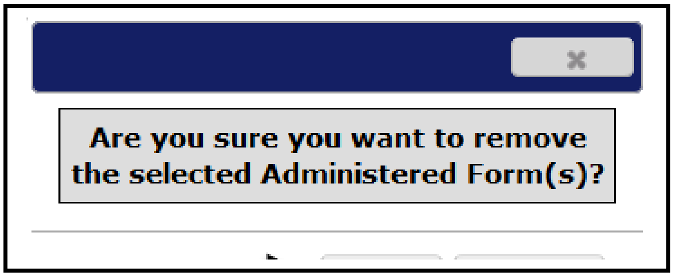
3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



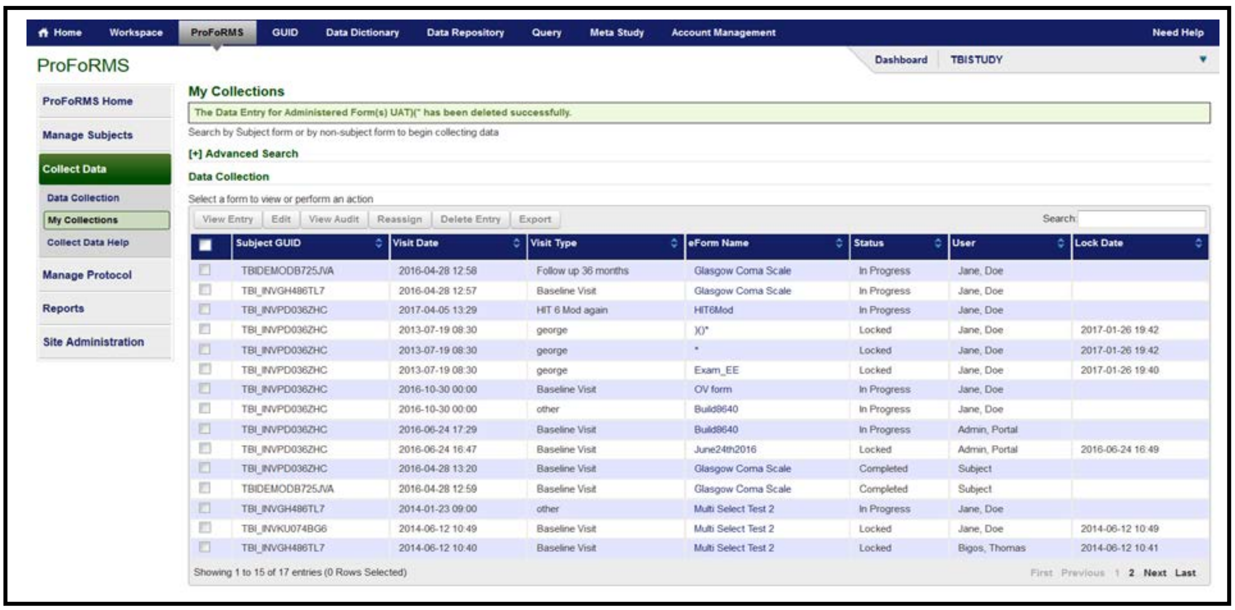
4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, select the Check-box next to the Subject you would like to delete. Click the **Delete Entry** button.



5. Click the **OK** button when prompted '**Are you sure you want to remove the selected Administered Form(s)?"**



6. The **My Collections** page appears with the confirmation of the deleted Data Entry form updated.



ICON KEY

Notes

Important Information

Things to Note:

Below details the different scenarios and users who have the ability to delee a data collection:

In Progress Status:

- Global Admin
- ProFoRMS Admin
- Nonadmin users with privileges to delete collections
- Owners of the data collection

Completed Status:

- Global Admin
- ProFoRMS Admin
- Nonadmin users with privileges to delete collections
- Owners of Data Collection

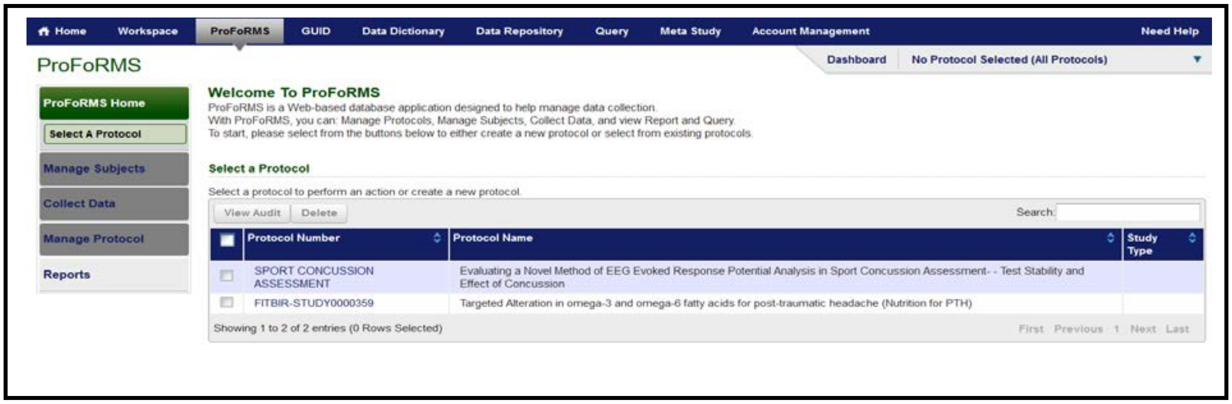
Locked Status:

- Global Admin
- ProFoRMS Admin

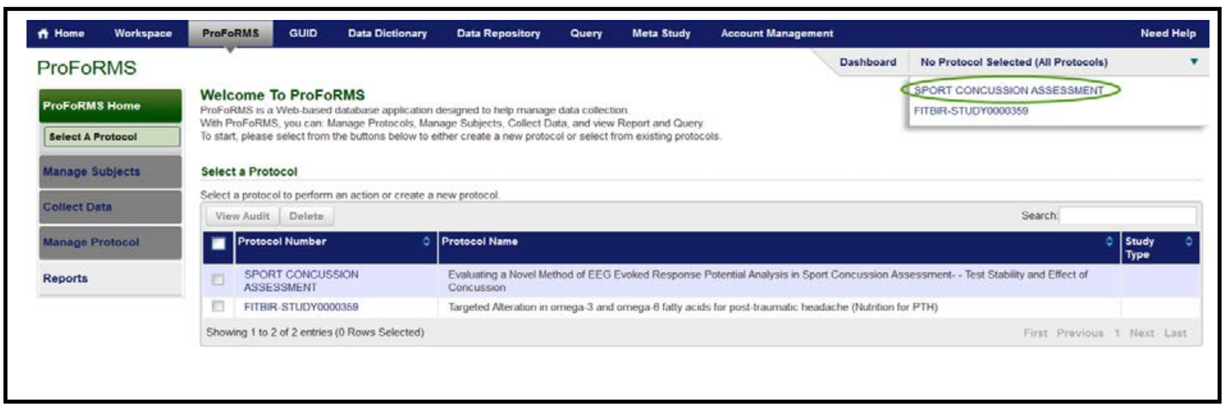
3.7.2 Exporting Data Collections

To Export Data Collections: Perform the following actions:

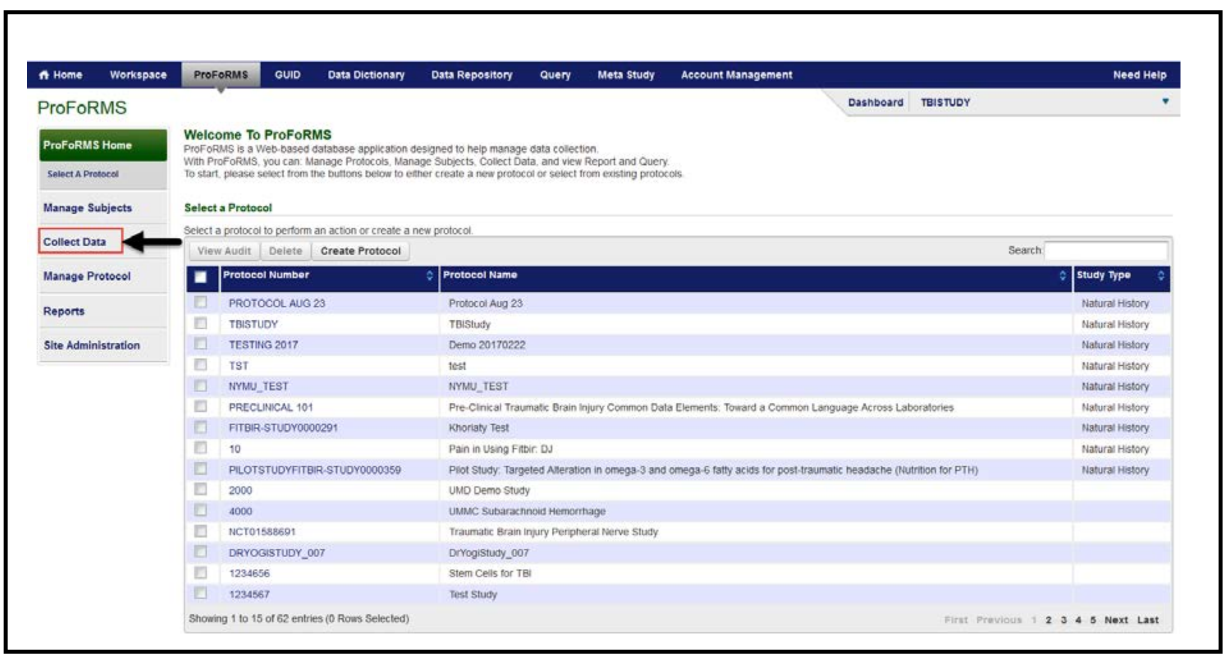
1. Navigate to the **ProFoRMS** module



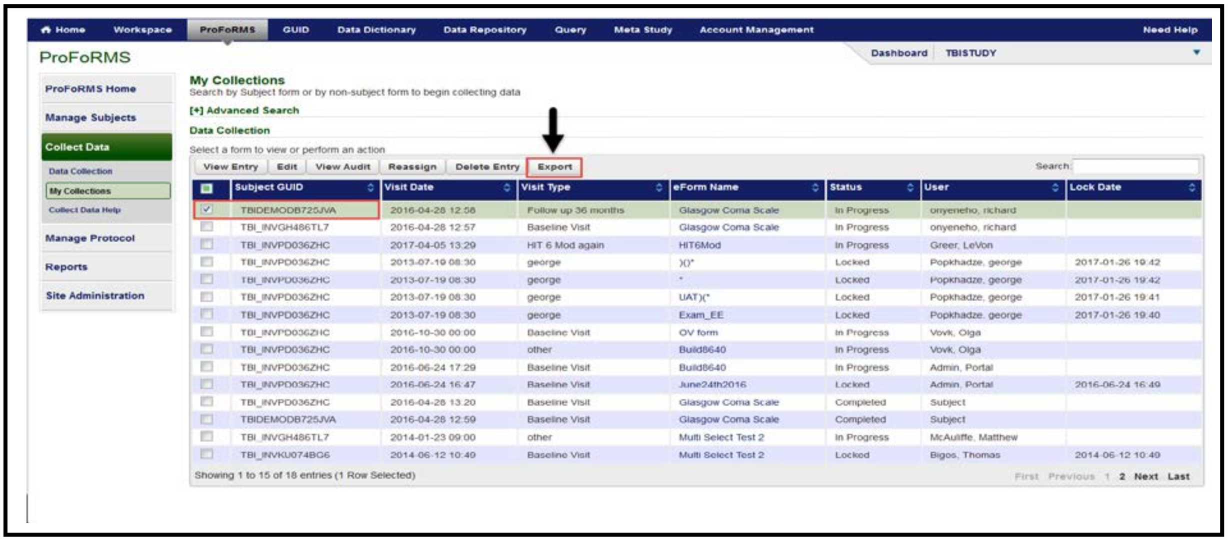
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



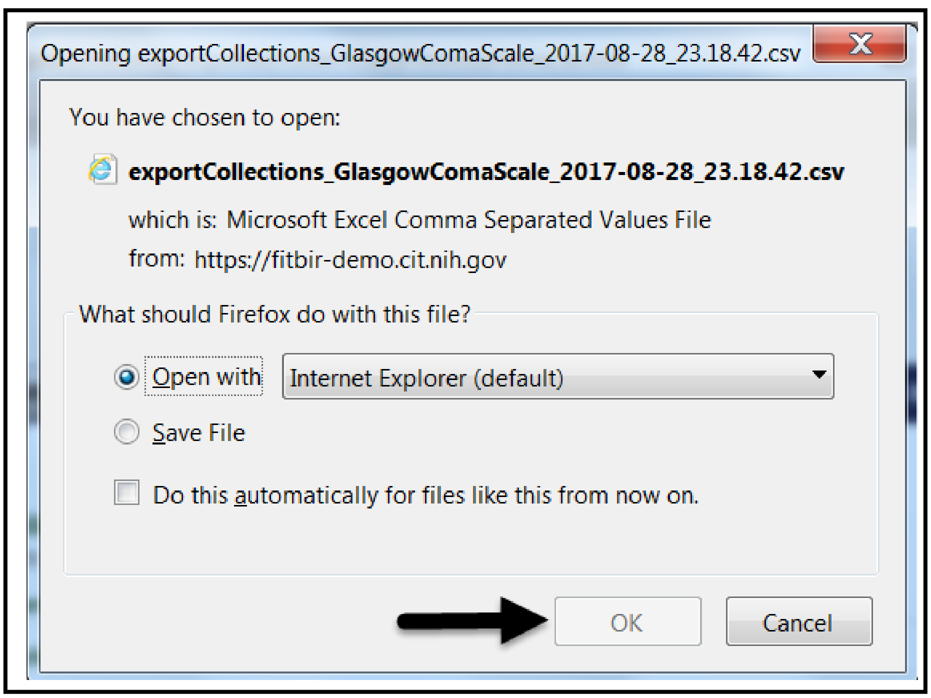
3. The ProFoRMS Dashboard opens. Click the **Collect Data** on the left-side tool bar.



4. Click the **My Collection** on the left-side tool bar. The **My Collections** page appears with listings of collections. On the **My Collections** page, select the Check-box next to the Subject you would like to export. Click the **Export Entry** button.



5. Select the **Open with** Internet Explorer (default) option and Click **OK** button to launch the CSV file.



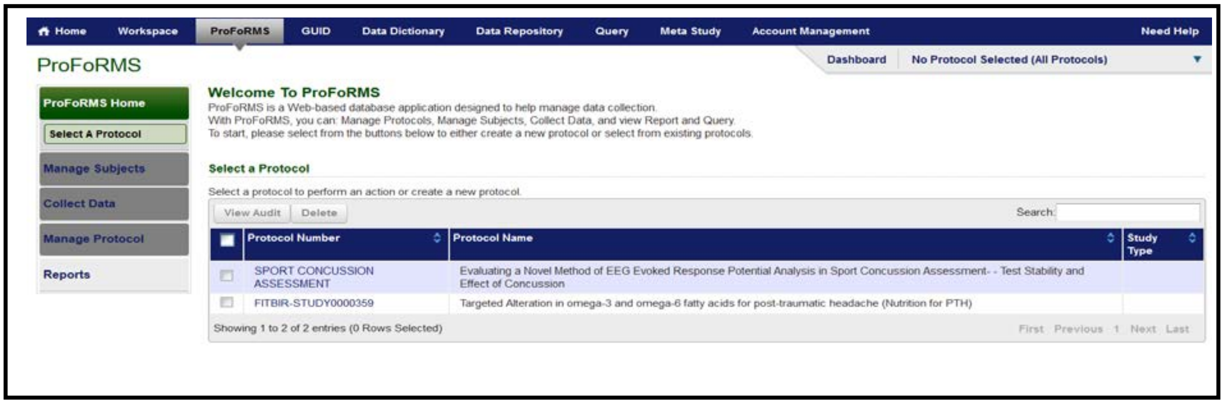
3.8 Manage Protocol

This feature is designed to help the researchers to add and edit study information, schedule create study visits, manage visit types individual subjects across multiple studies within the system, upload subject related document.

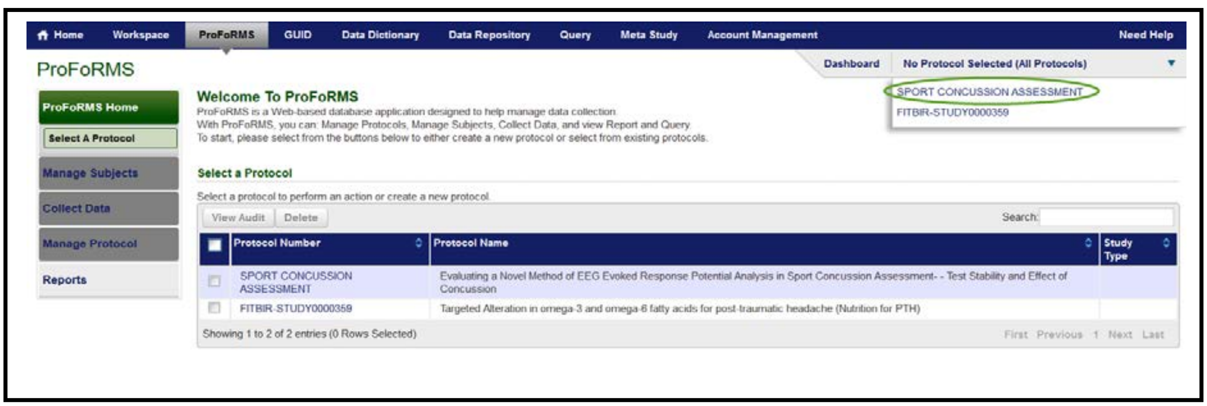
3.8.1 Viewing Protocol Information

To view Protocol information: Perform the following actions:

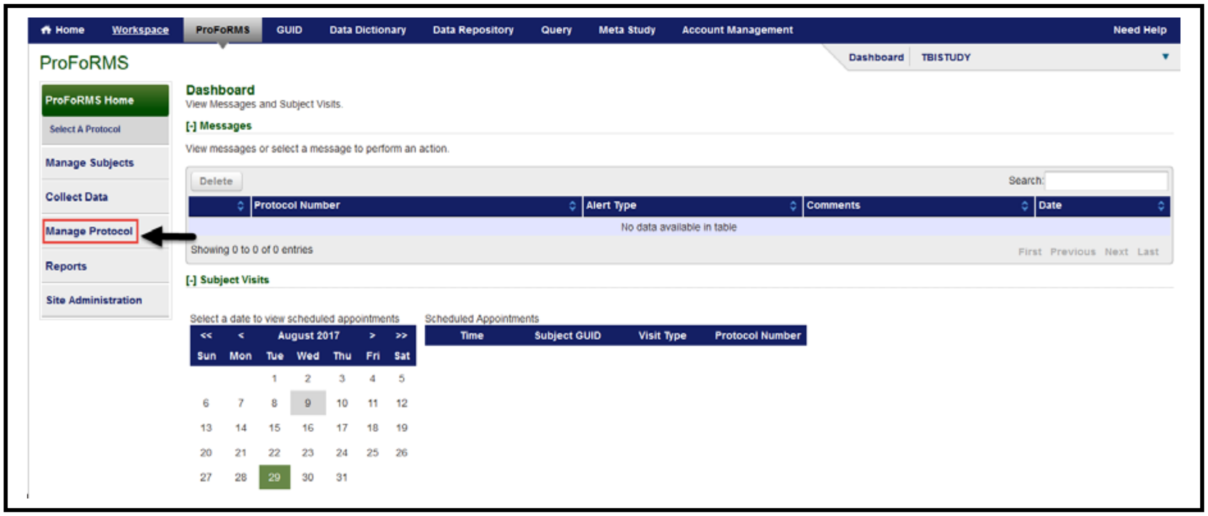
1. Navigate to the **ProFoRMS** module



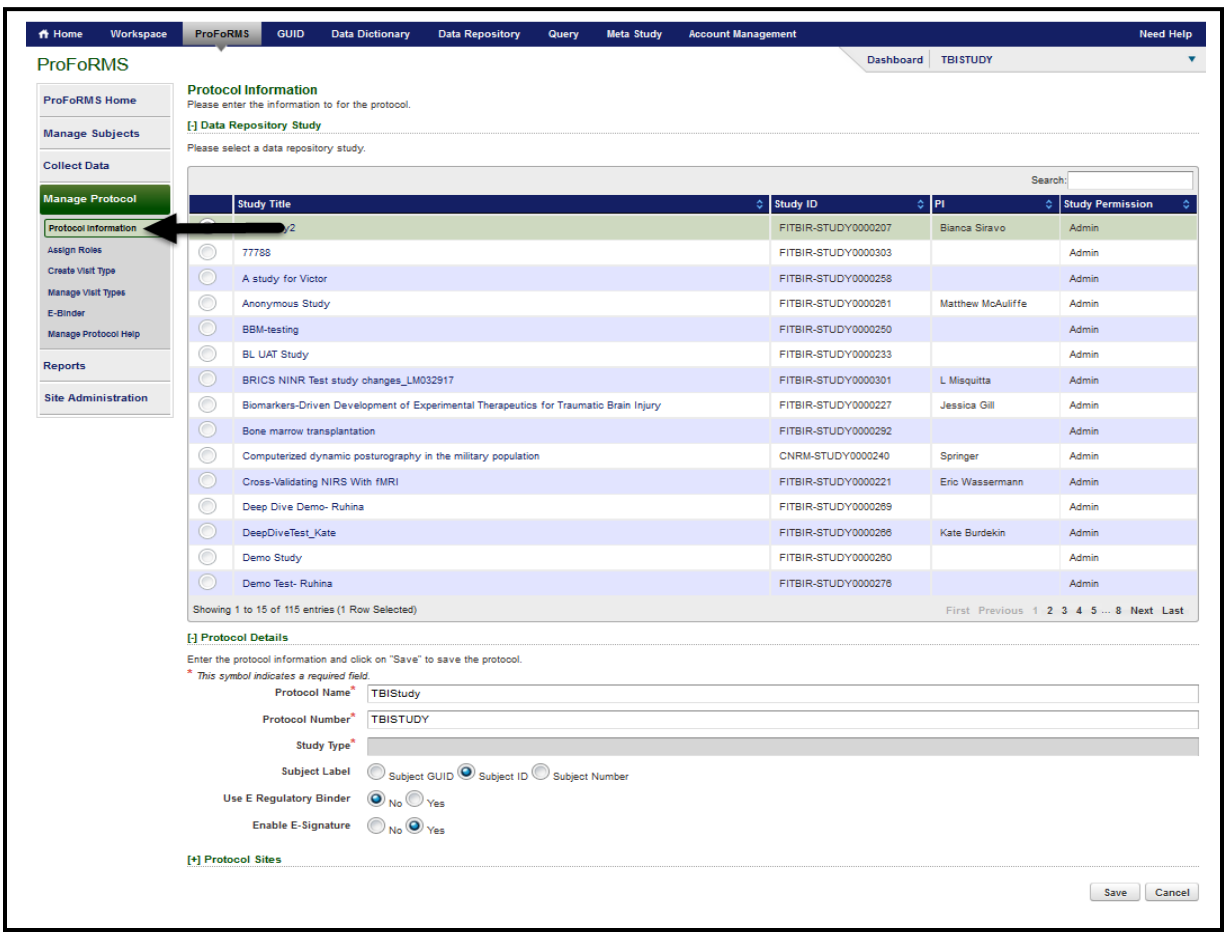
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



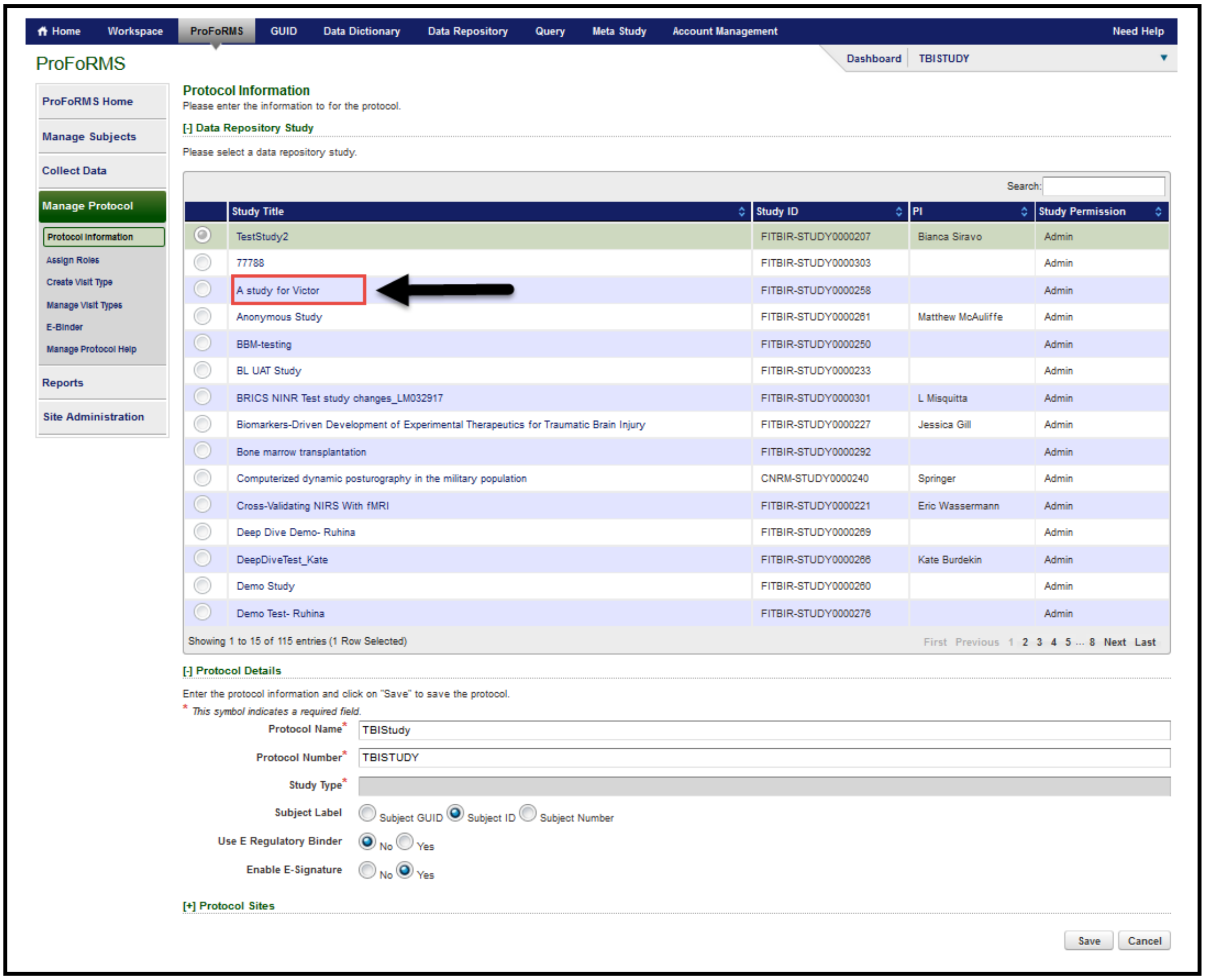
3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



4. Click the **Protocol Information** on the left-side tool bar. The Study Information page appears.



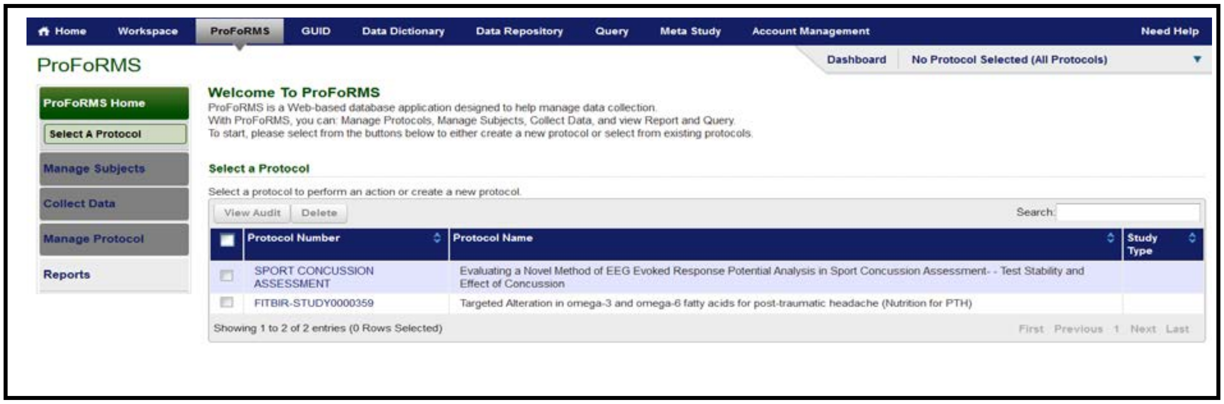
5. Click the **Study Title** to open the Protocol.



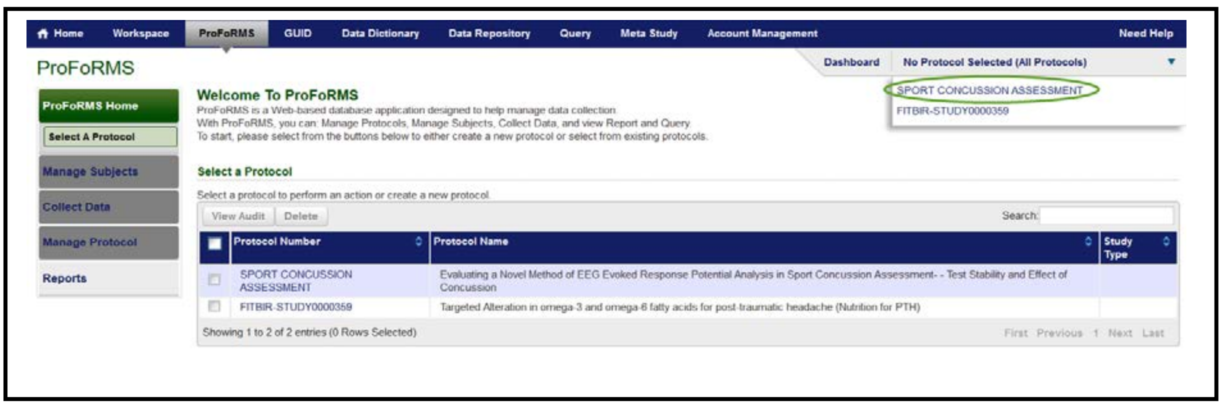
3.8.2 Assign Roles

To assign roles within a study: Perform the following actions:

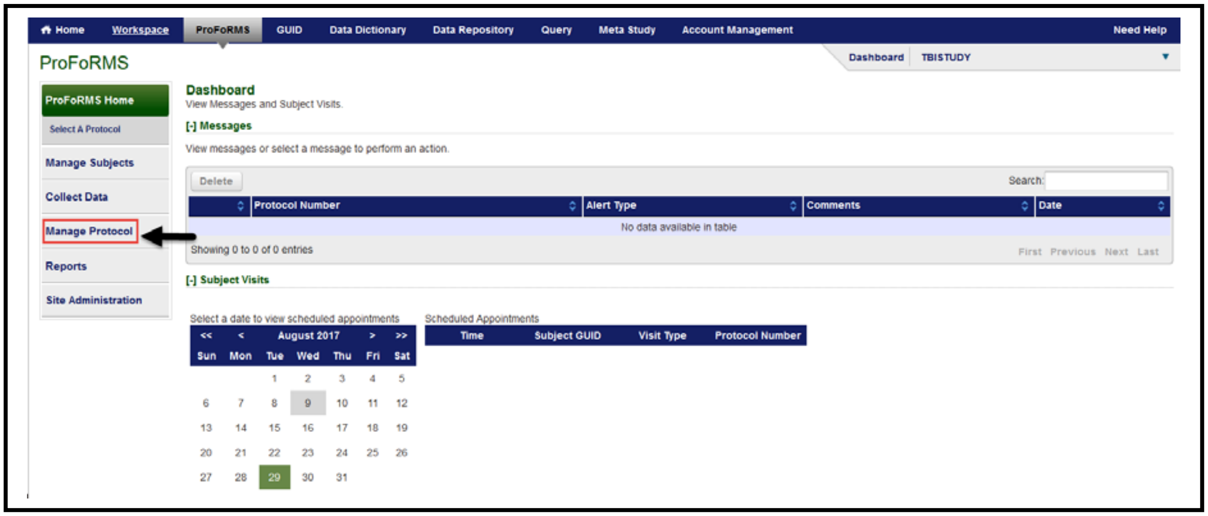
1. Navigate to the **ProFoRMS** module



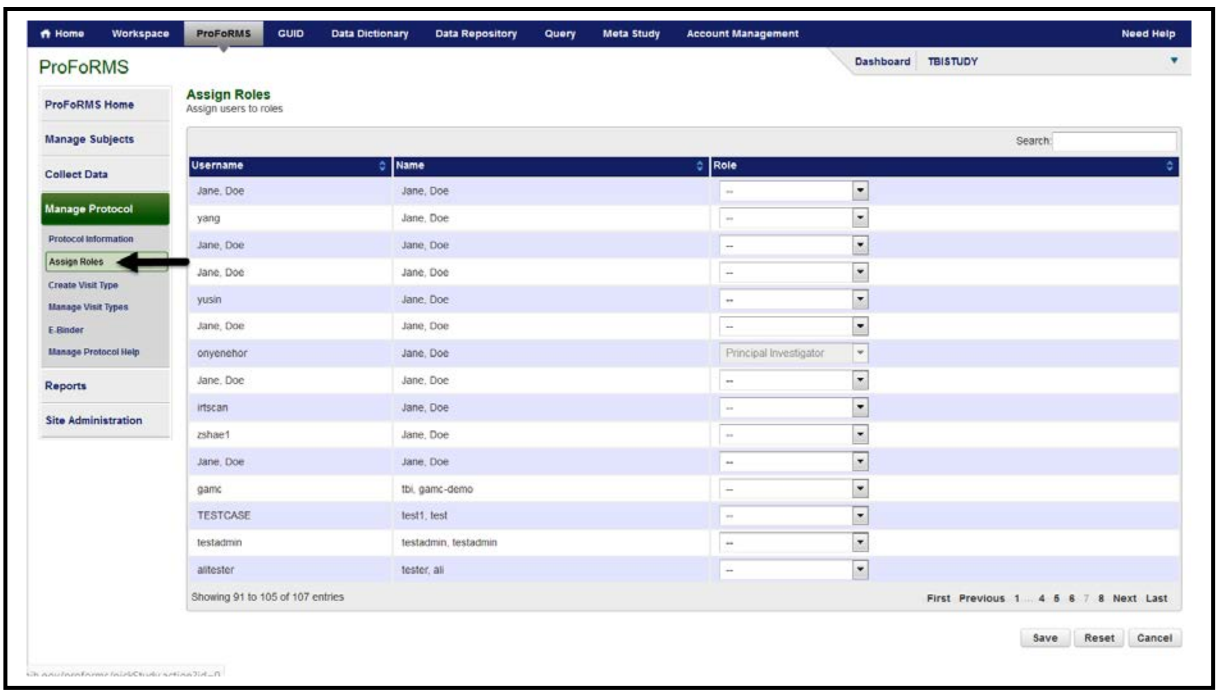
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



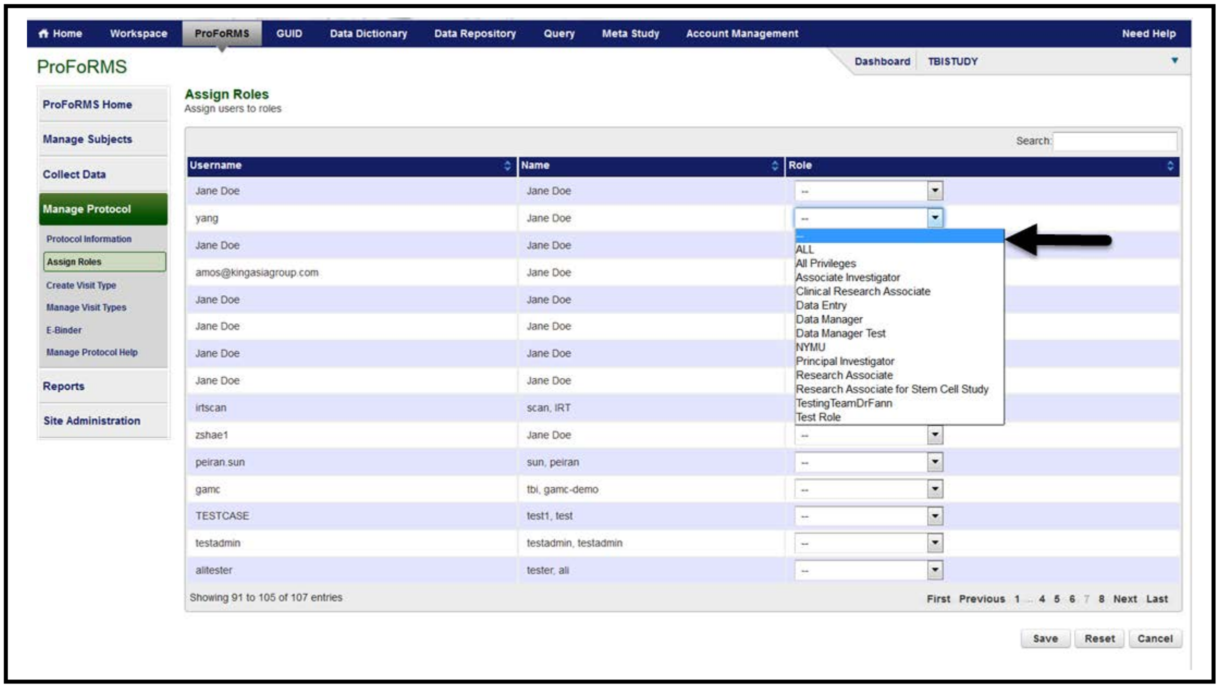
3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



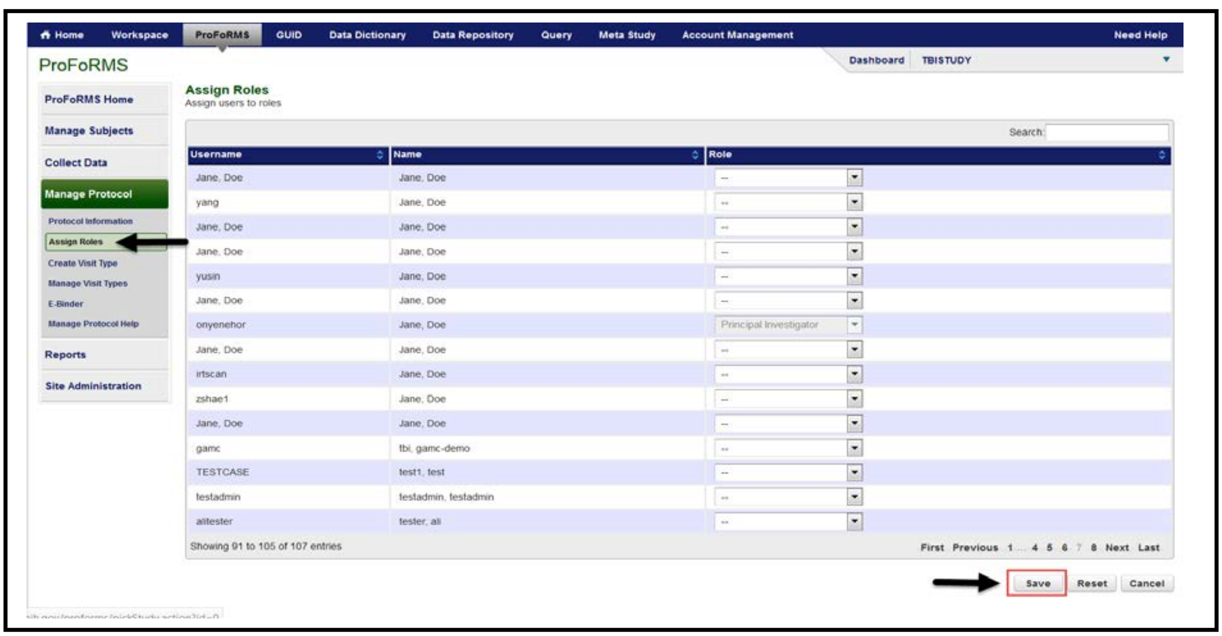
4. Click the **Assign Roles** button on the left-side tool bar. The Assign Roles page appears.



5. In the **Assign Roles** page, find a user from the list of users. Use the drop-down menu to select and assign roles for a user in that study. The user roles depend on the study set up and can be as follows: Principal Investigator (max privileges), Clinical Coordinator, Study QA, Data Entry, etc.



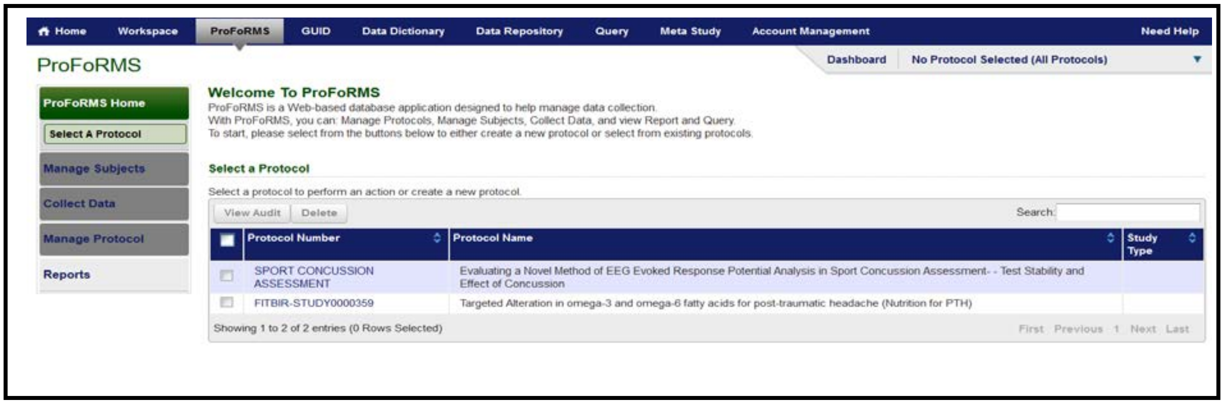
6. Click the **Save** button. The new user role(s) appear in the protocol set up.



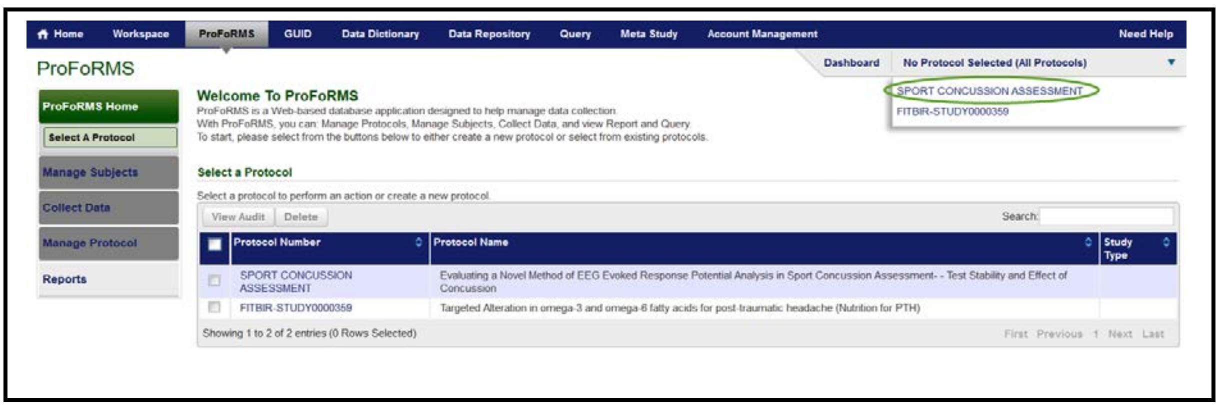
3.8.1 Manage Visit Types

To manage visit types: Perform the following actions:

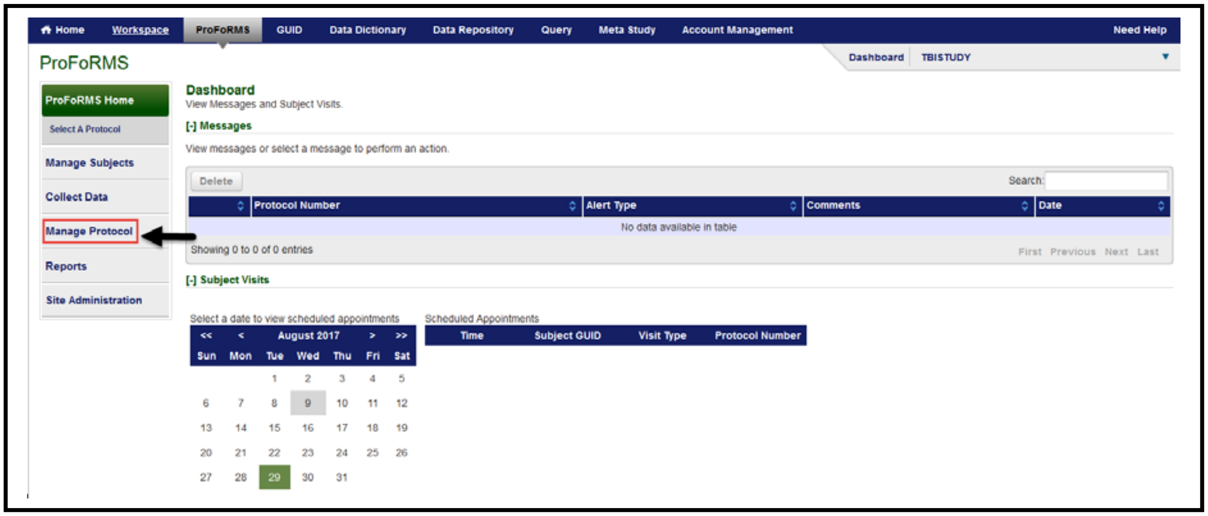
1. Navigate to the **ProFoRMS** module



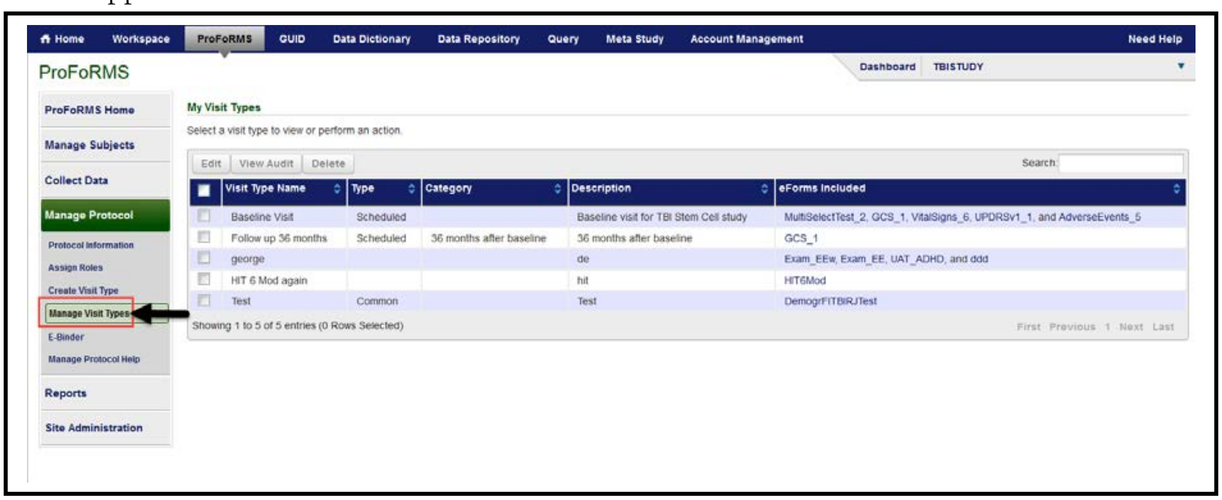
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



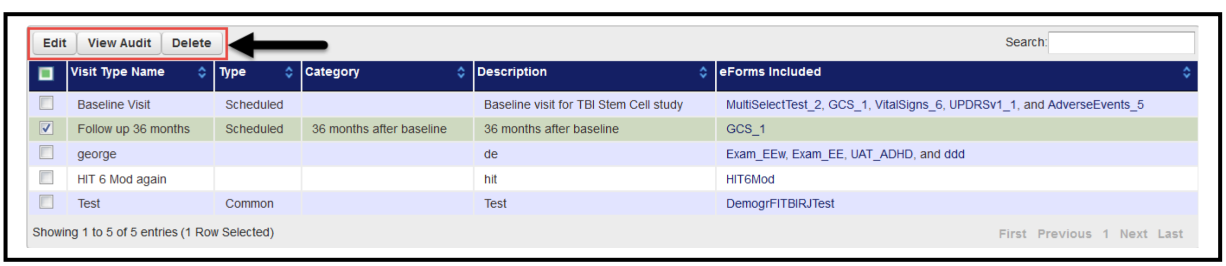
3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



4. Click the **Manage Visit Types** button on the left-side tool bar. The My Visit Types page appears.



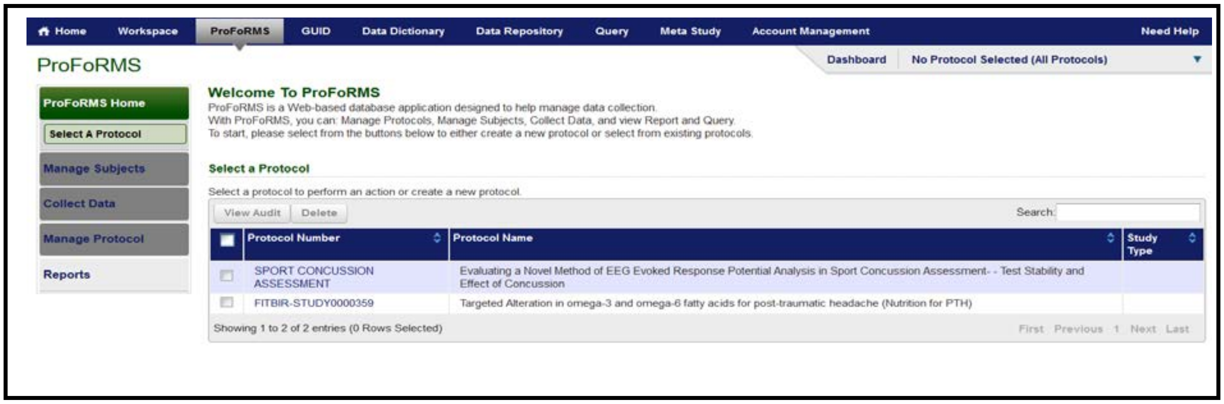
5. Select the Check-box beside the **Visit Type Name** to perform an action: **Edit**, **View Audit** and **Delete** functions.



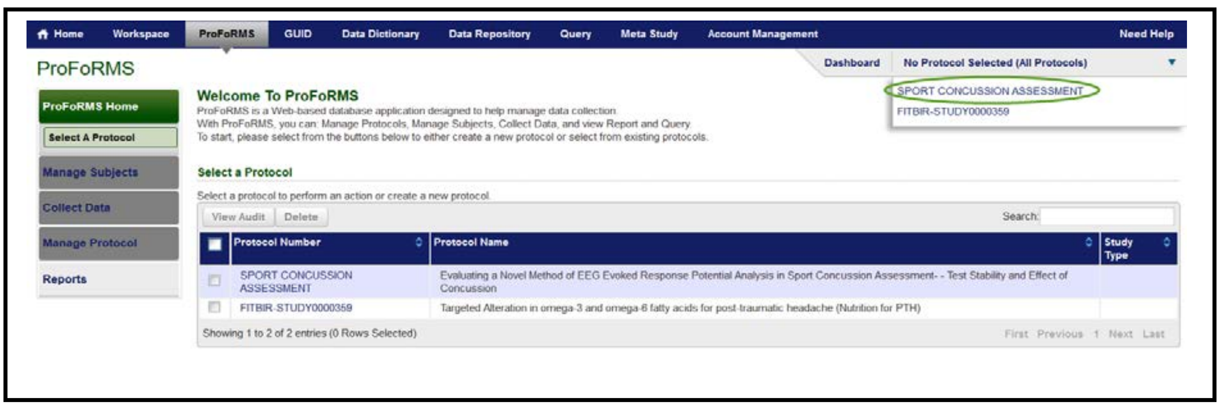
3.8.2 Create Visit Types

To create visit types: Perform the following actions:

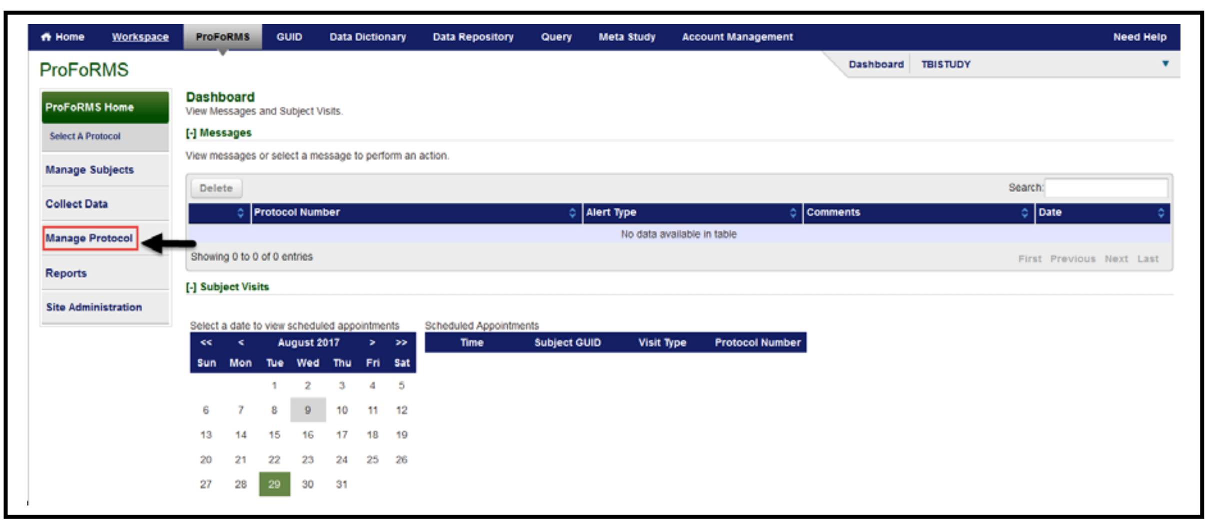
1. Navigate to the **ProFoRMS** module



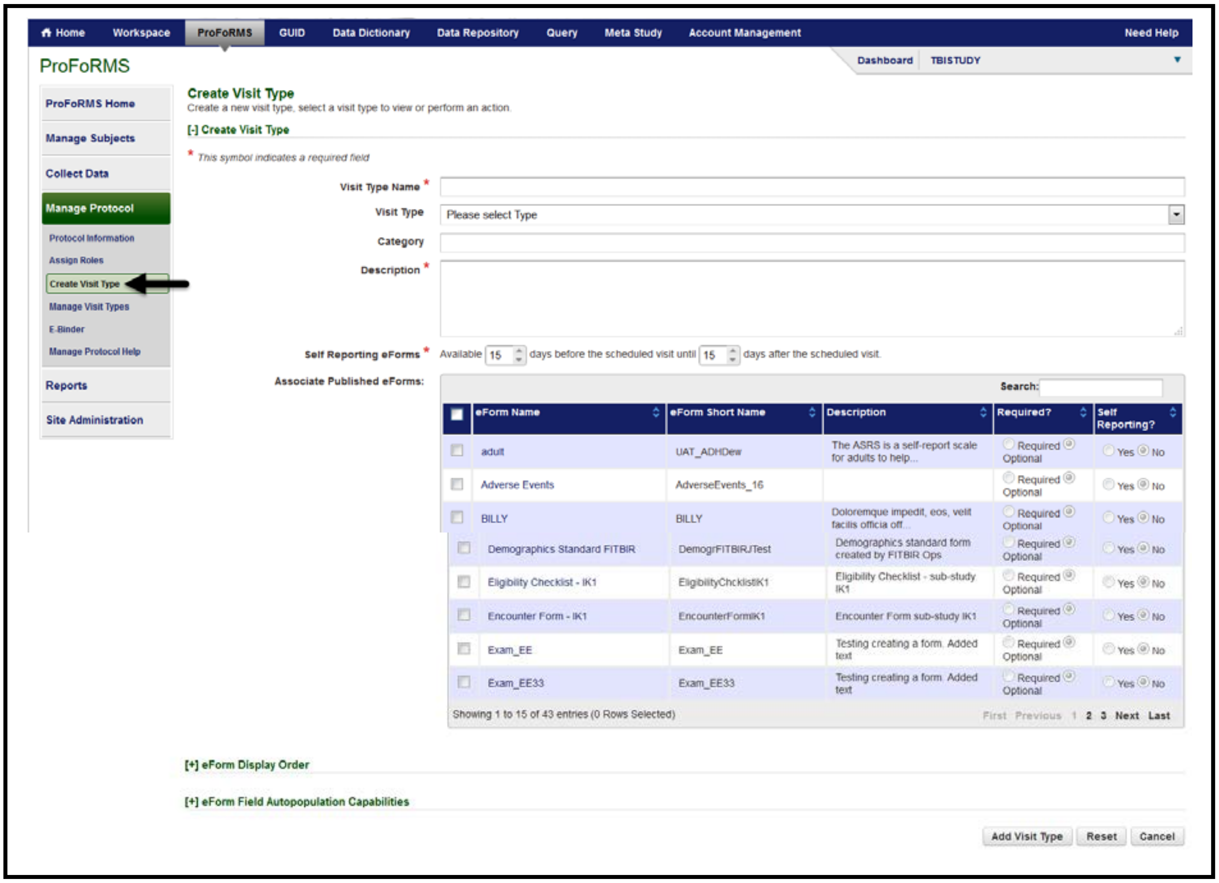
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.

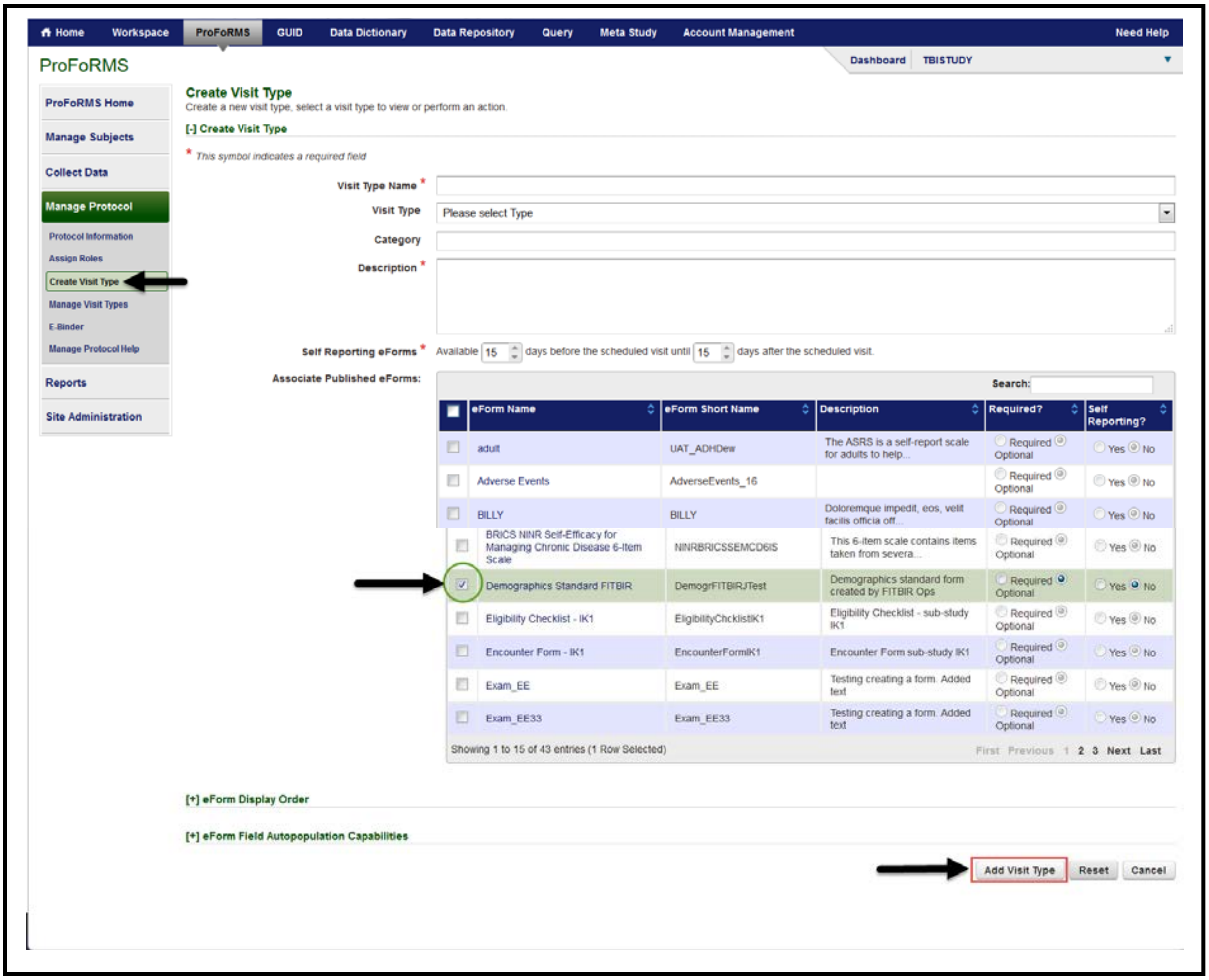


4. Click the **Create Visit Type** button on the left-side tool bar. The Create Visit Type page appears.

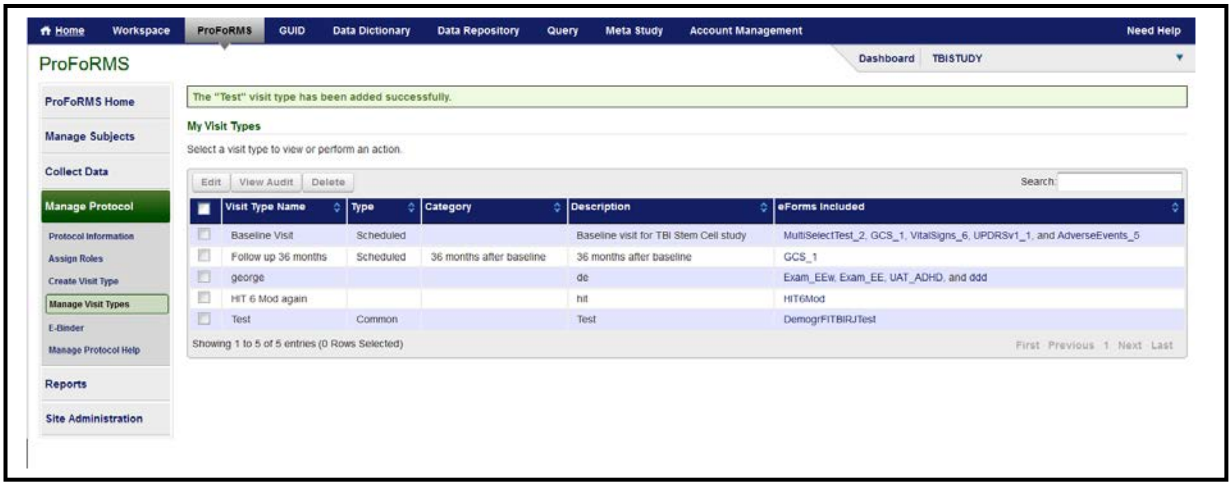


5. Create a new visit type by entering the **Visit Type Name**, **Visit Type**, and a **Short Description**. Associate published eForms to your visit by selecting the **check-box** beside the **eForm Name**, Select the check-boxes beside the eForm(s) to associate published eForms. Then, use the up and down button to change the order under: " **(-) eForm Display Order**" The list only contains the eForms that are selected within the visit type.

   Finally, the fields within the eForms associated with this visit type have the ability to be autopouplated during data collection period after they are autopoulated. Select the fields to enable autopopulation within this visit type under "**(+) eForm Autopulation capabilities**". You may have to provide additional information when scheduling a visit for a particular subject. Click the **Add Visit Type** button.



6. The new visit type(s) appears in the **My Visit Type** page.

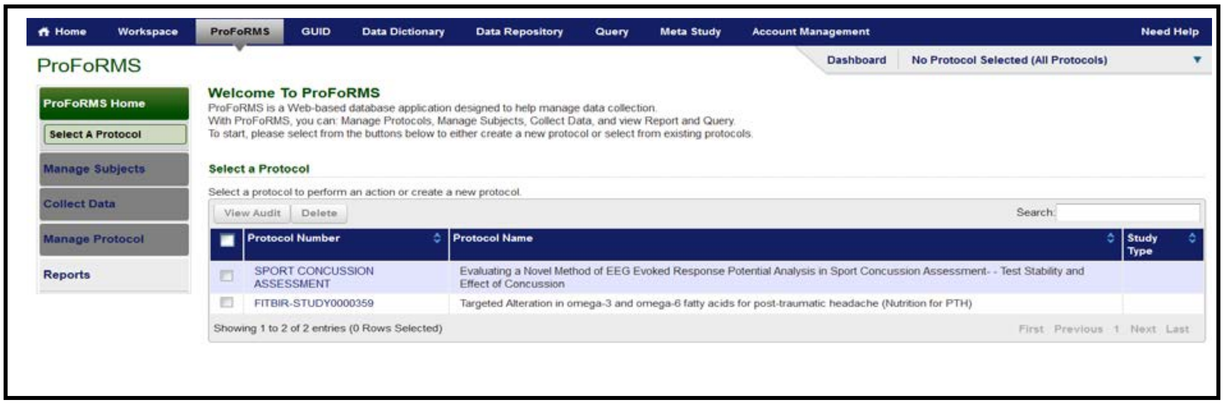


3.8.3 Patient Self Reporting (PSR)

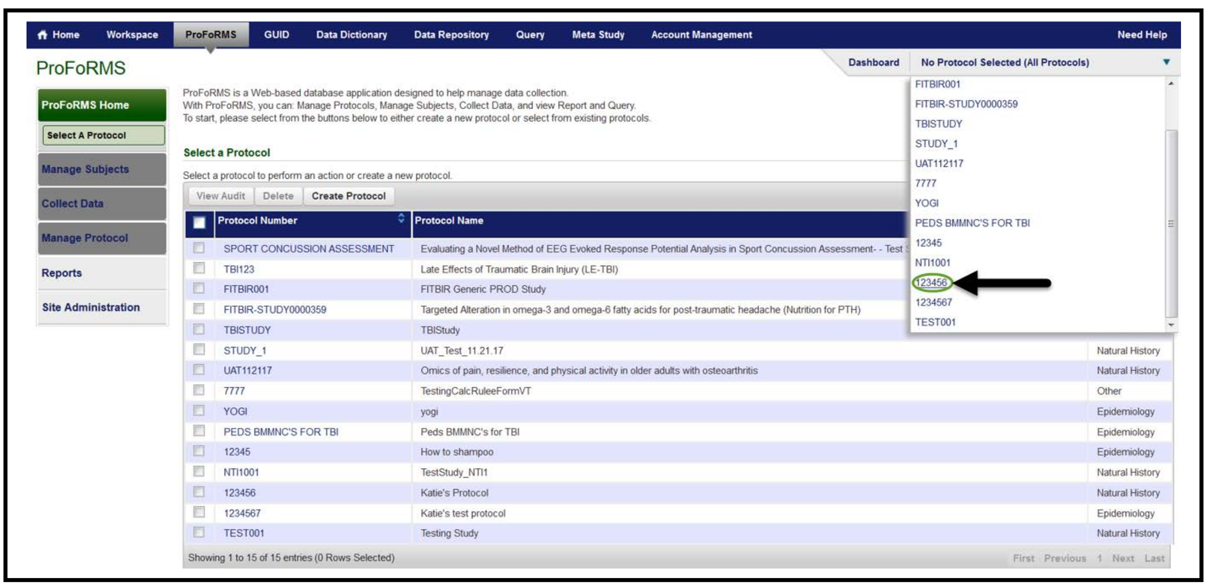
Patient Self-Reporting is an Admin-enabled function. You must have an administrative privilege in order to use this feature. Ensure you have Administrative privileges enabled before attempting to set up patient self-reporting in ProFORMS.

To view Performance Overview Report: Perform the following actions:

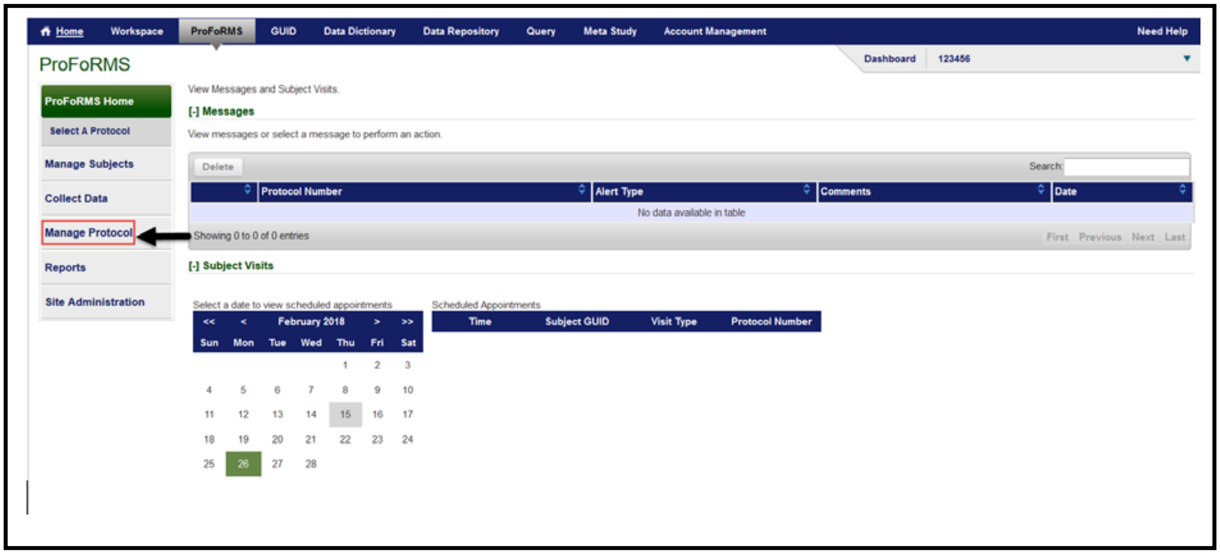
1. Navigate to the **ProFoRMS** module



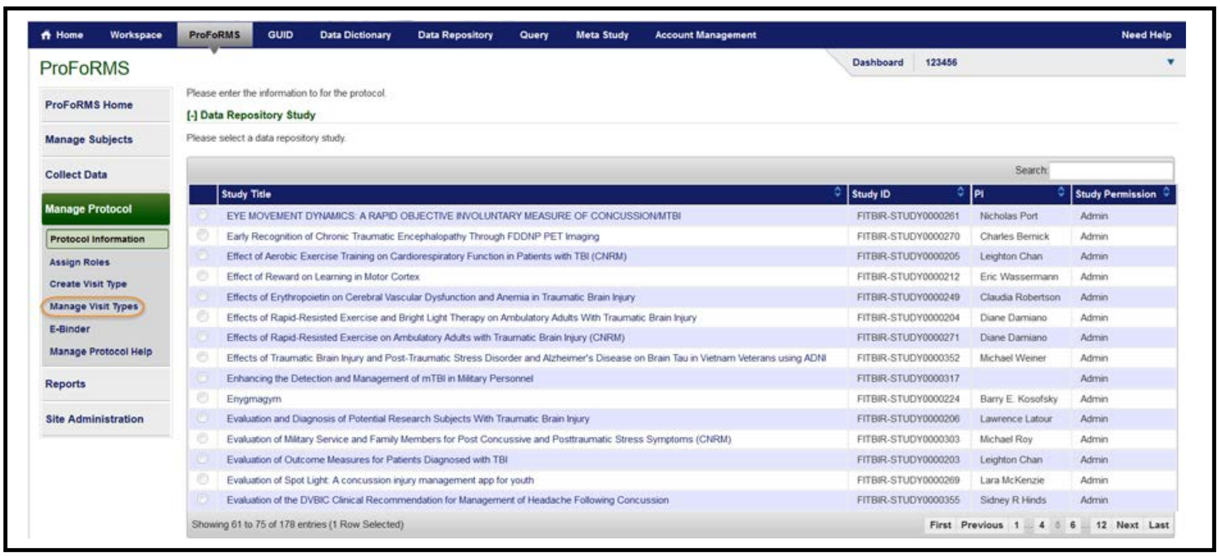
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



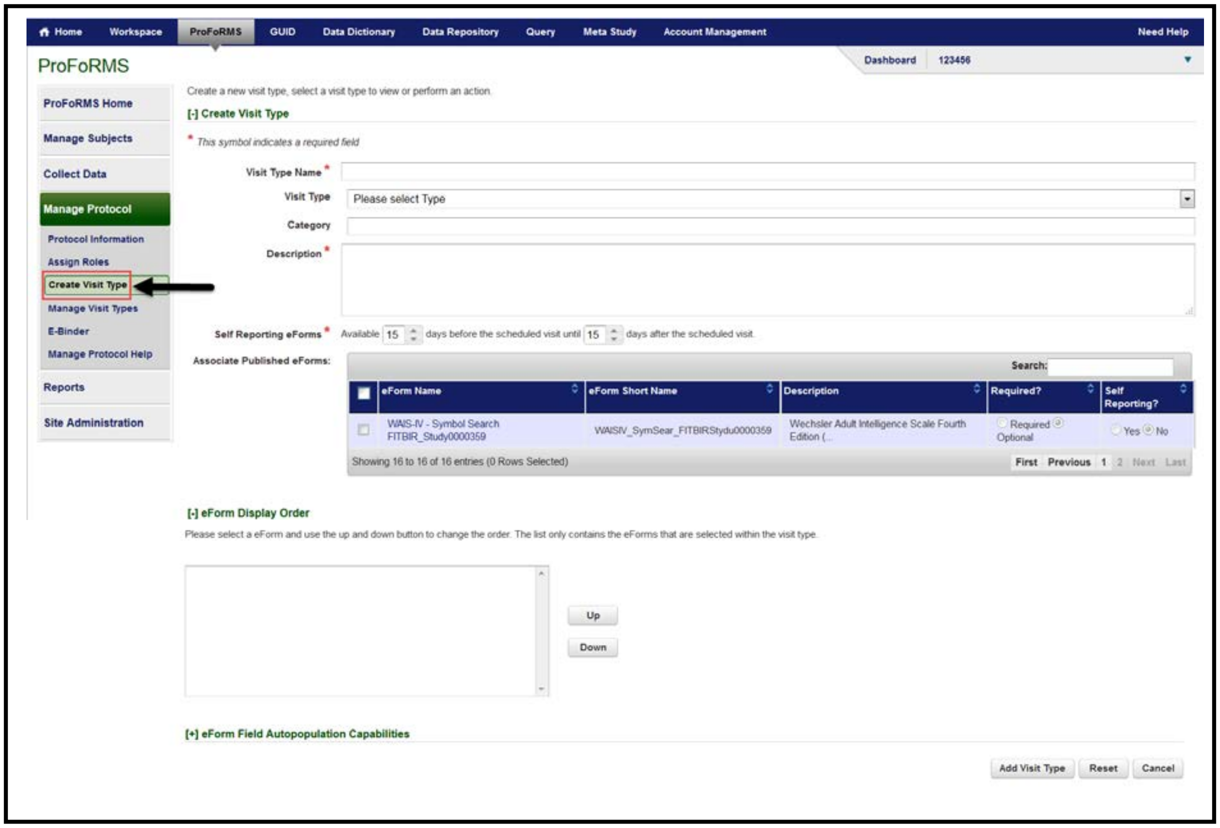
3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



4. Click the **Manage Visit Types** button on the left-side tool bar. The **My Visit Types** page appears.



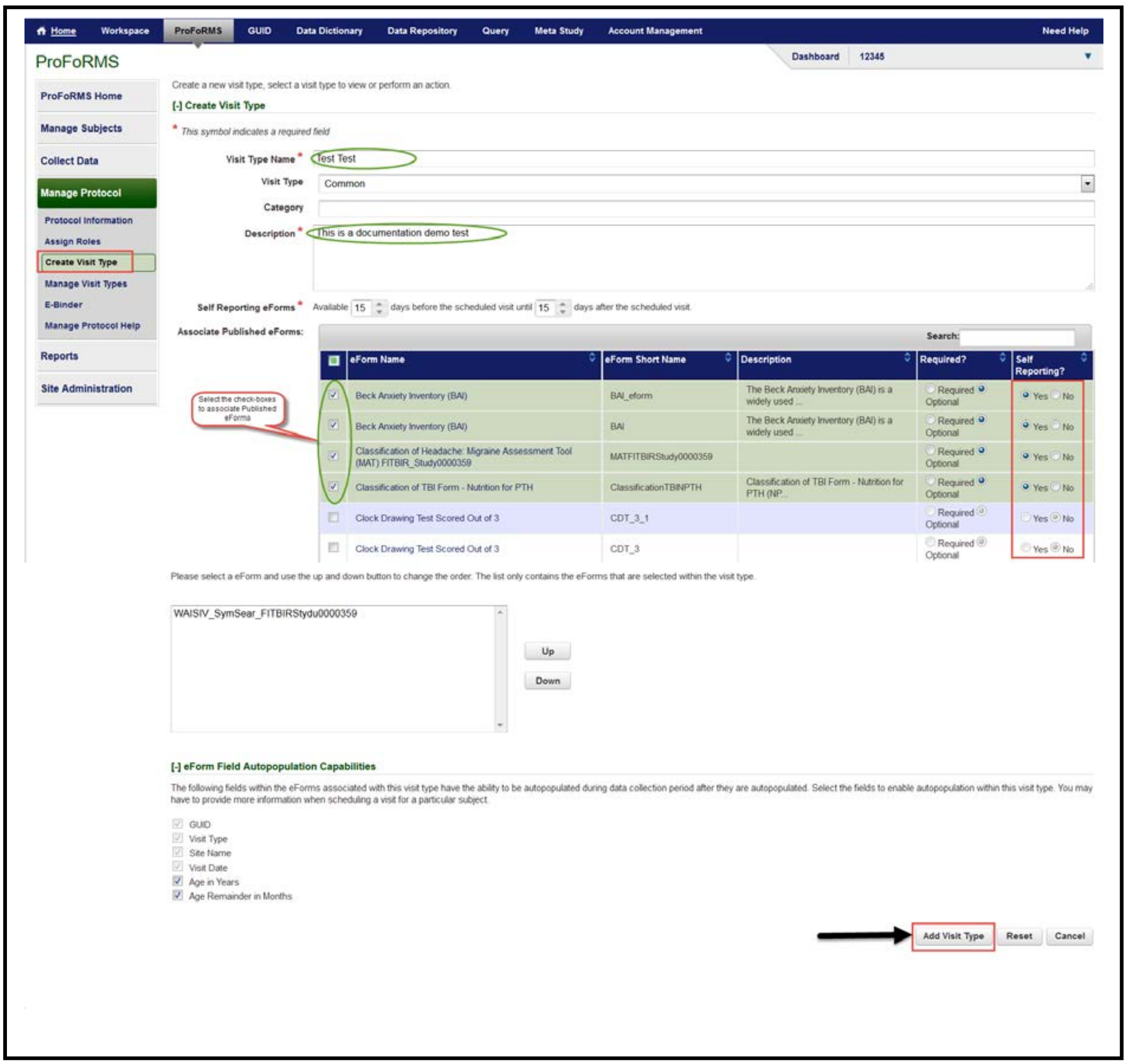
5. Click **Create Visit Type** button on the left-side tool bar. The **Create Visit Type** page appears.



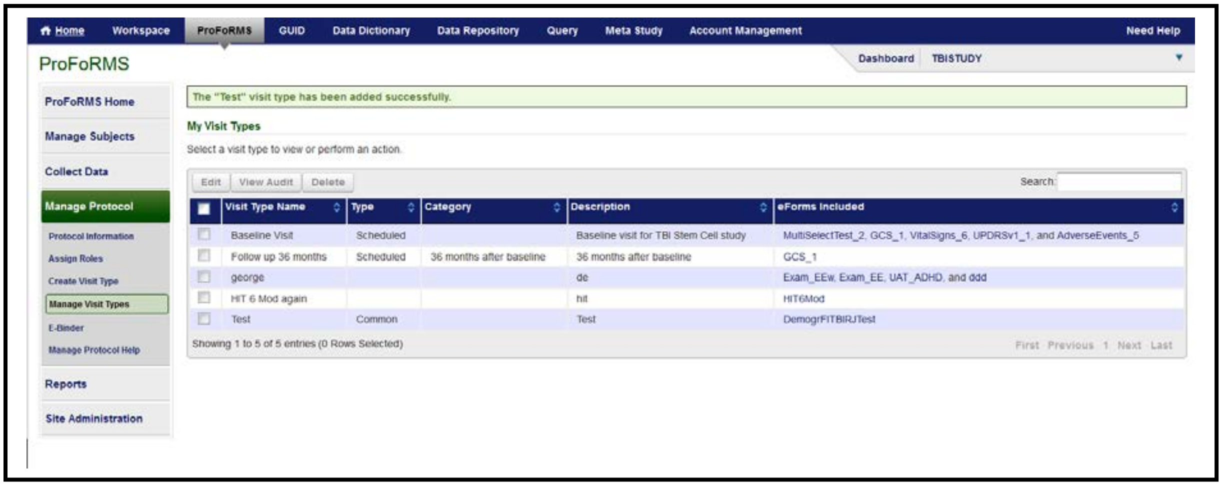
6. Create a new visit type by entering the **Visit Type Name**, **Visit Type**, and a **Short Description**. Associate published eForms to your vist by selecting the **check-box** beside the **eForm Name**, Select the **Yes** under **Self Reporting**. Select the check-boxes beside the eForm(s) to associate published eForms. Under the "**Self Reporting**" column, select the check-box beside "**Yes**".

   Then, use the up and down button to change the order under: " **(-) eForm Display Order**" The list only contains the eForms that are selected within the visit type.

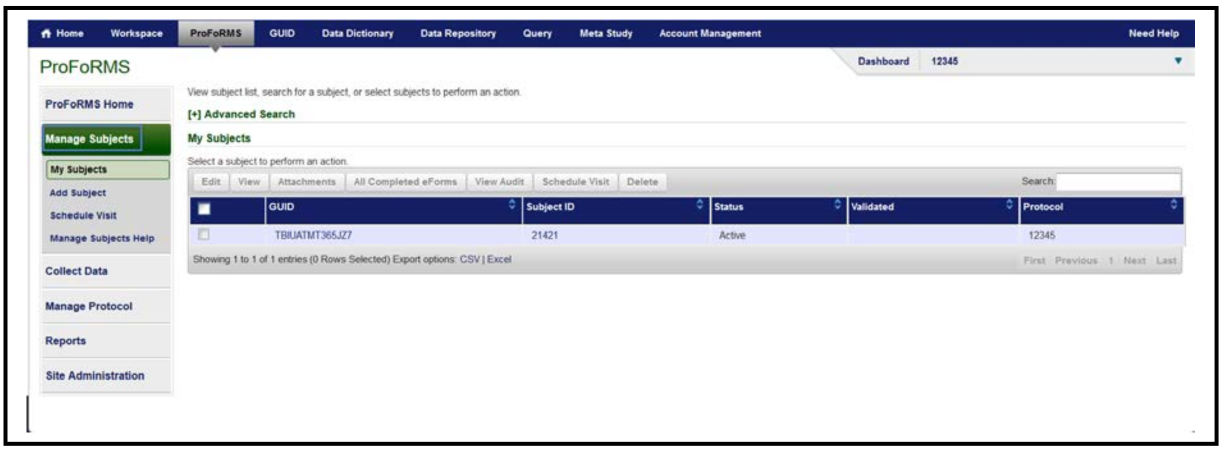
   Finally, the fields within the eForms associated with this visit type have the ability to be autopouplated during data collection period after they are autopoulated. Select the fields to enable autopopulation within this visit type under "**(+)eForm Autopulation capabilities**". You may have to provide additional information when scheduling a visit for a particular subject. Click the **Add Visit Type** button.



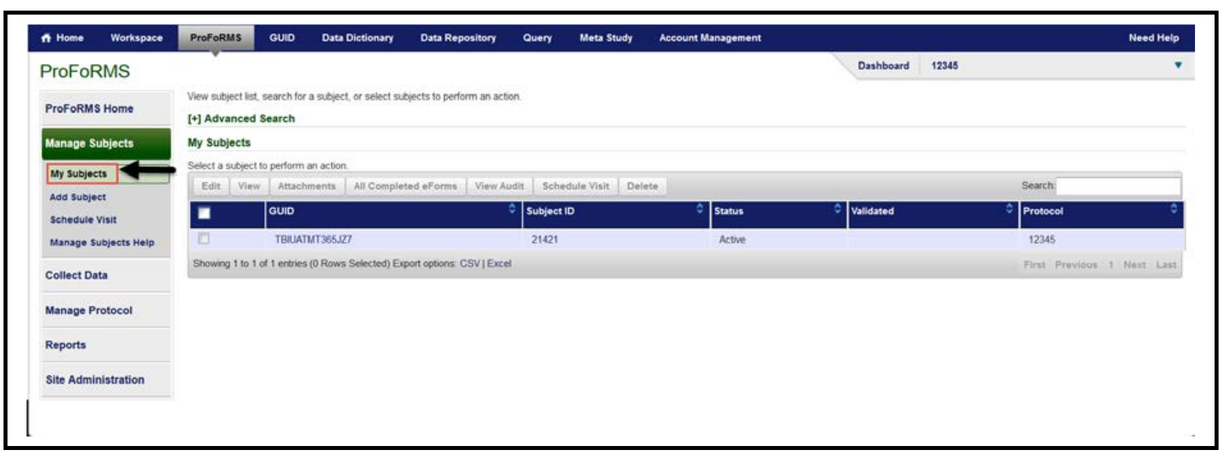
7. The new visit type(s) appears in the "**My Visit Type**" page.



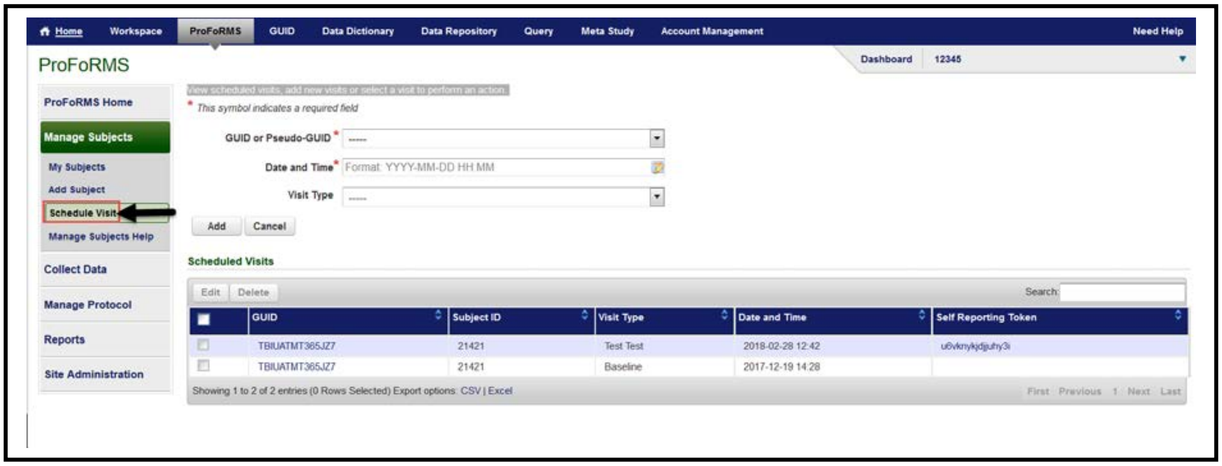
8. Click on **Manage Subjects** button on the left-side tool bar.



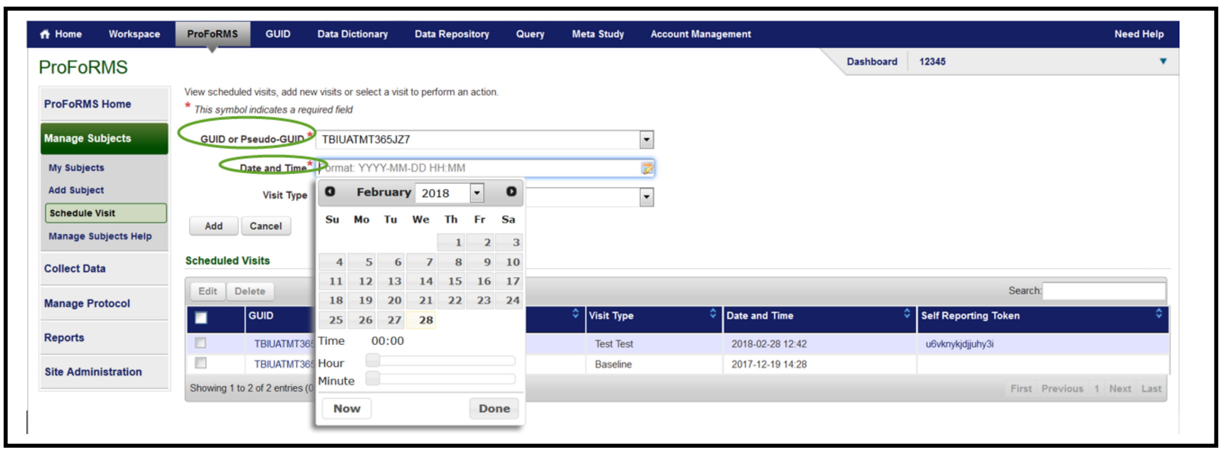
9. Click on **My Subjects** on the left-side tool bar.



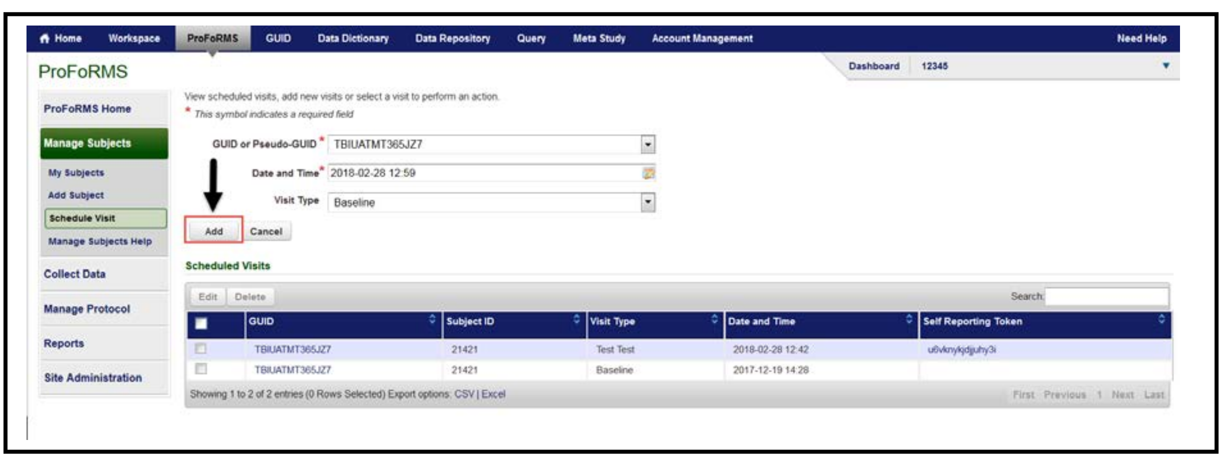
10. Click the **Schedule Visit** button on the left-side tool bar.



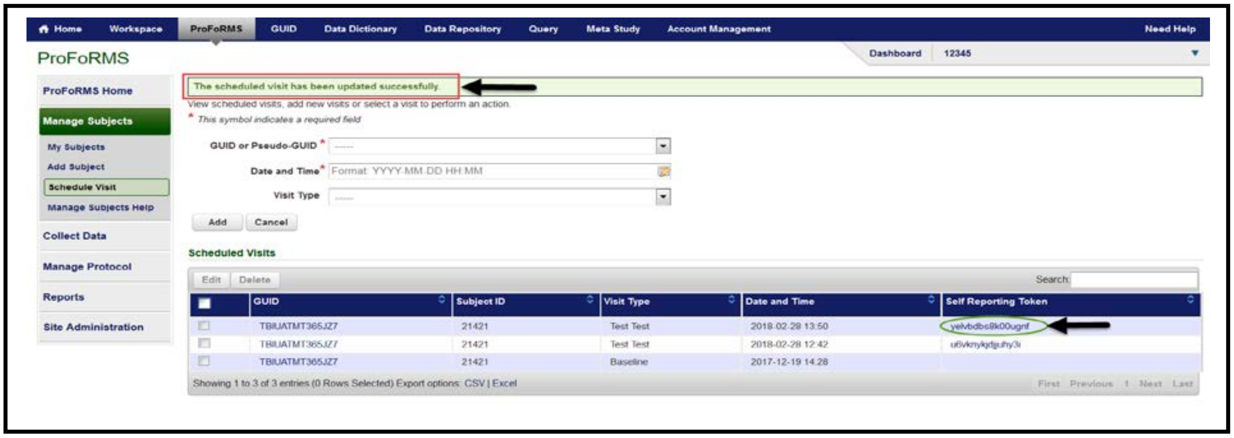
11. Add new visit or select a visit from the drop-down menu. * This symbol indicates a required field. Select the desired visit date by clicking on the calendar icon.



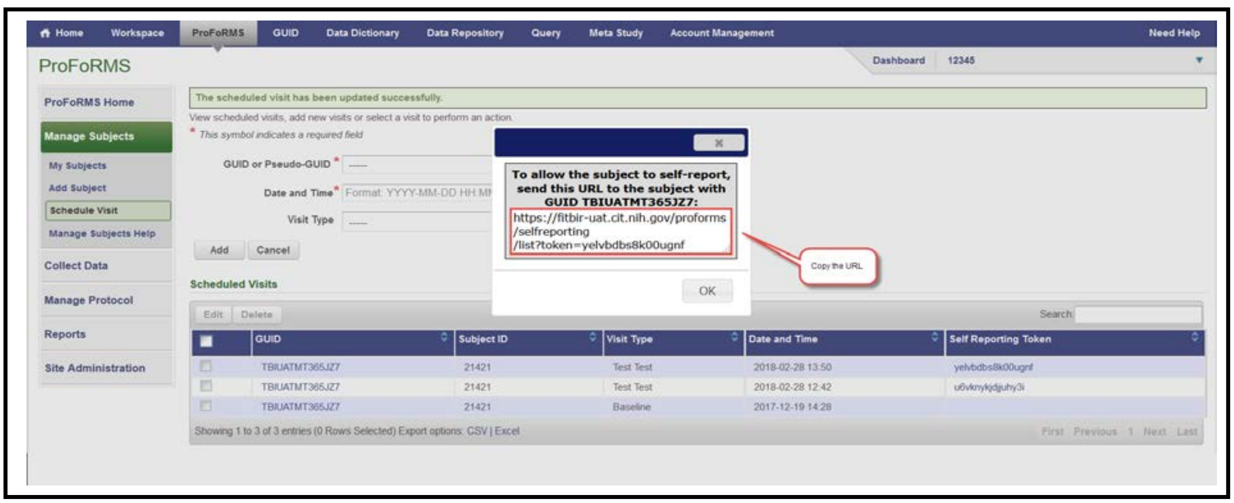
12. Click the **Add** button.



13. The scheduled visit will be updated successfully.



14. To allow the subject to self-report, click on the **Self-Reporting Token** link and send it to the subject with the GUID.

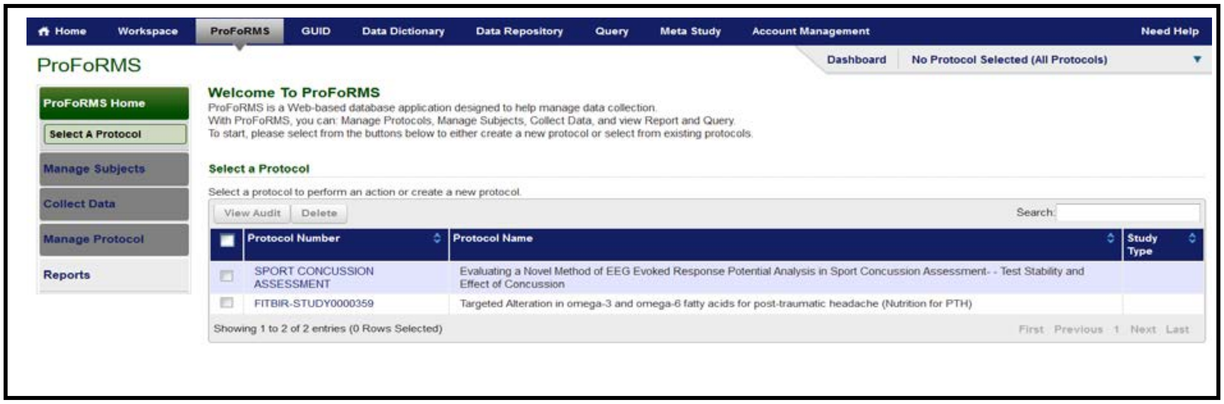


3.8.1 E-Binder

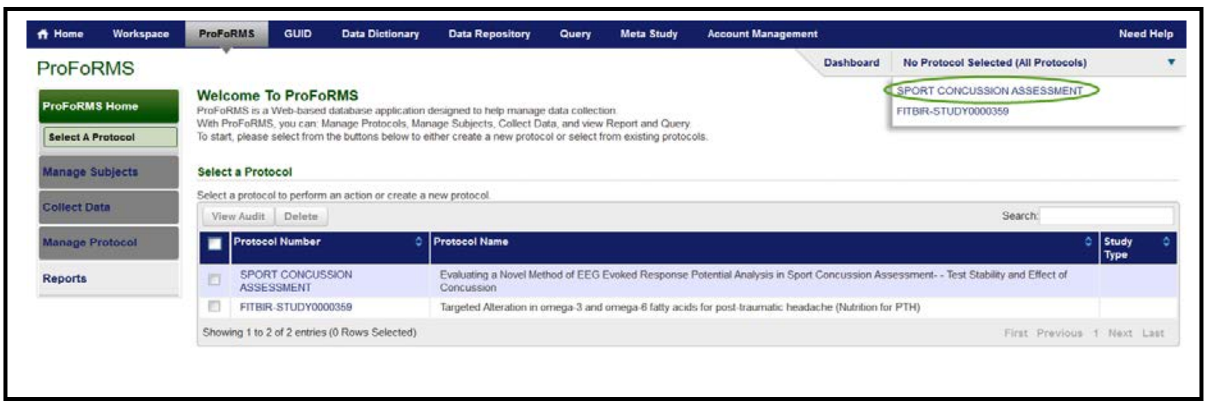
The E-Binder used to Add/Edit documents or view existing documents.

To access this feature: Perform the following actions:

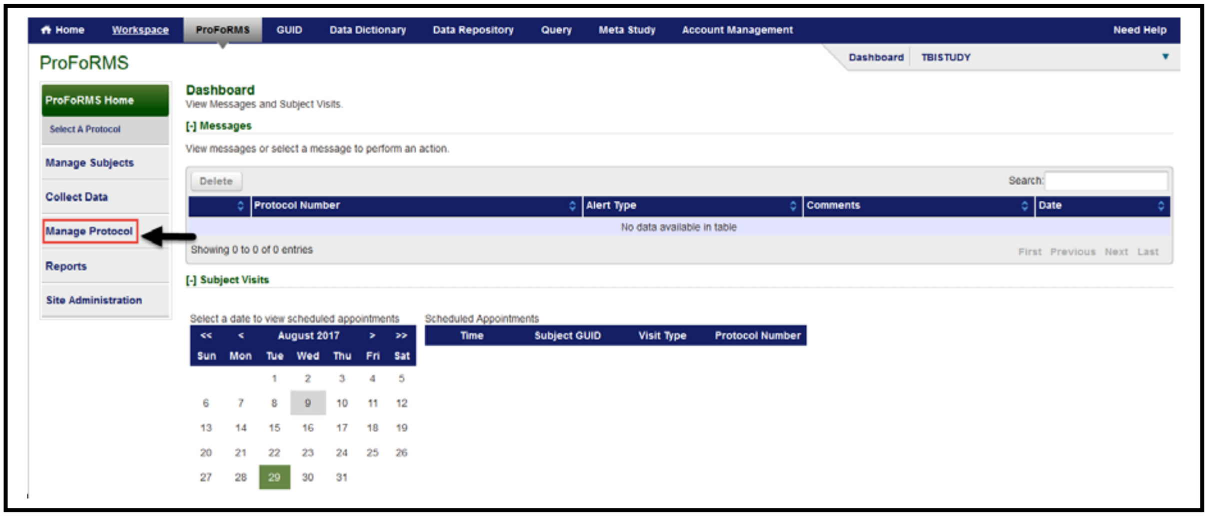
1. Navigate to the **ProFoRMS** module



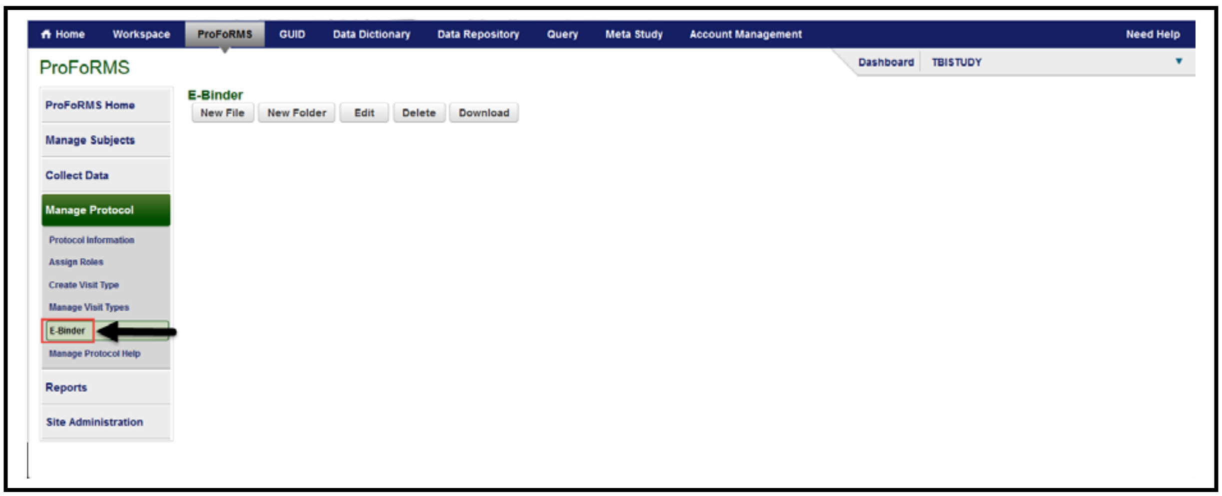
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Manage Protocol** on the left-side tool bar.



4. Click the **E-Binder** button on the left-side tool bar. The E-Binder page appears.



5. Use the **New File** option to upload a new document
6. Use the **New Folder** to create a new folder
7. Use the **Edit** option to edit your uploaded document
8. Use the **Delete** option to delete a document
9. Use the **Download** option to download documents.

3.9 Reports

The ProFoRMS reporting feature provides the following report outputs:

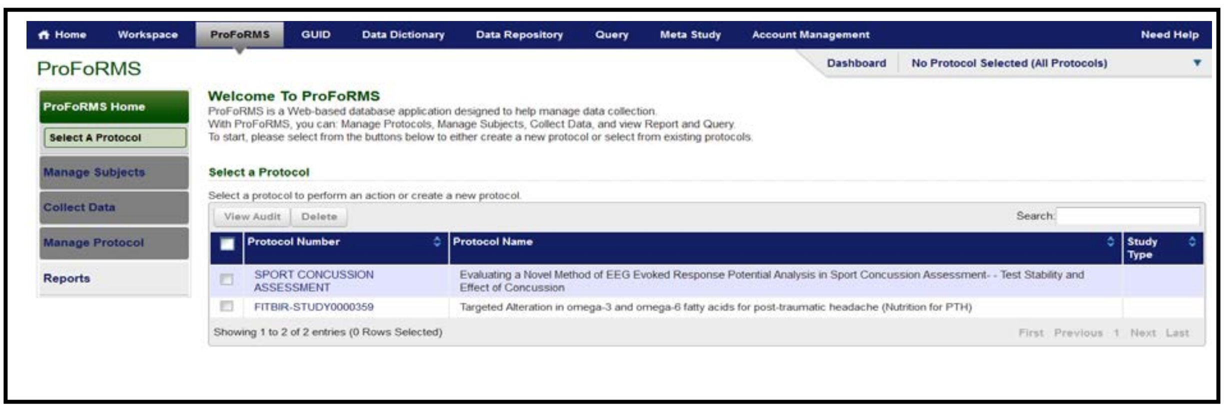
- Protocol Reports
- Completed Visits Report
- Performance Overview
- GUIDS Without Collections Report
- Forms Requiring Lock Report
- Locked Forms Report
- Form Status by GUID Report
- Submission Summary
- Form Status by GUID

3.9.1 Protocol Report

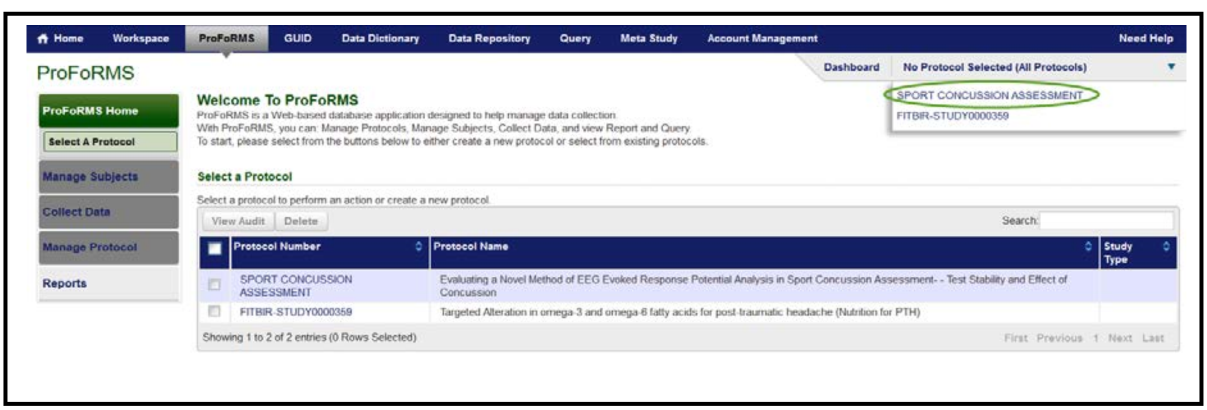
This report will show the protocol by Name, Principal Investigator, Protocol Type, Status, Number of Subjects Enrolled, and Number of Administered Forms of each protocol.

To view Protocol Report: Perform the following actions:

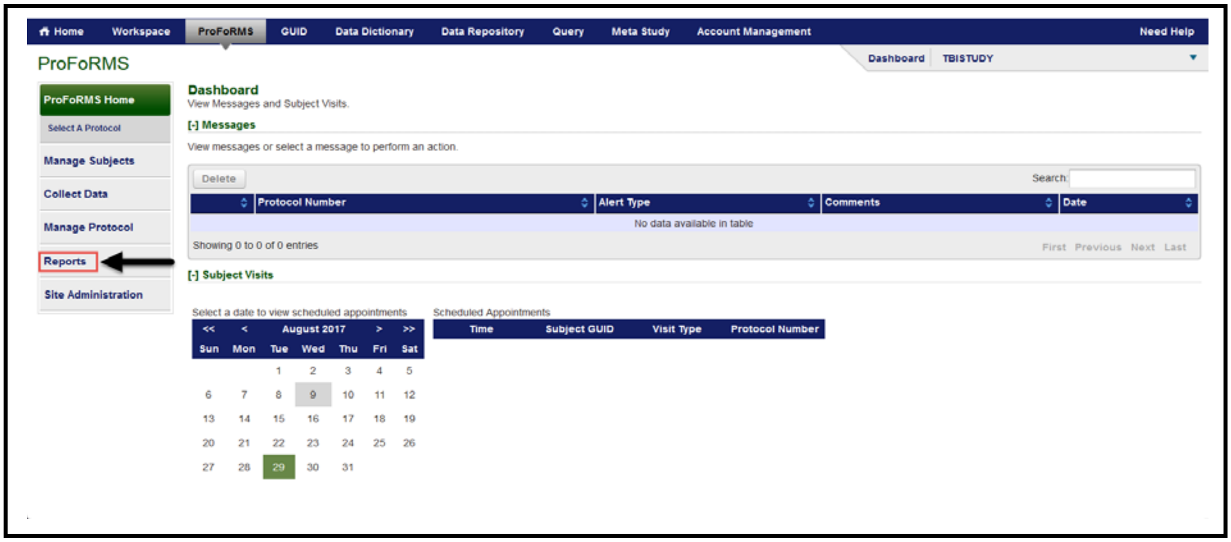
1. Navigate to the **ProFoRMS** module



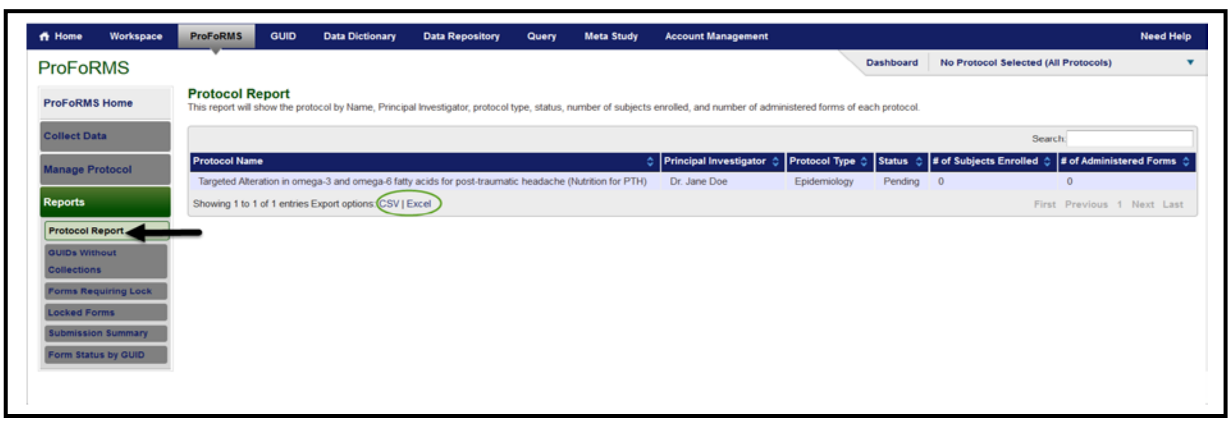
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



4. Click the **Protocol Report** on the left-side tool bar. The Protocol Report Information page appears. The report appears showing the Protocol Name, Principal Investigator, Protocol Type, Status, Number of Subjects Enrolled, and Number of Administered forms of each protocol. You may use the export feature to export the report to either CSV or Excel formats.

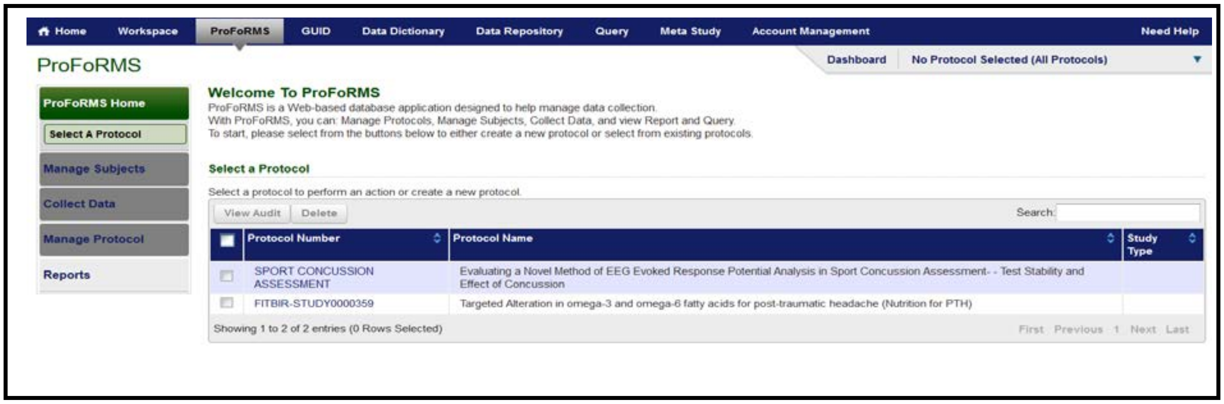


3.9.2 GUIDS Without Collections Report

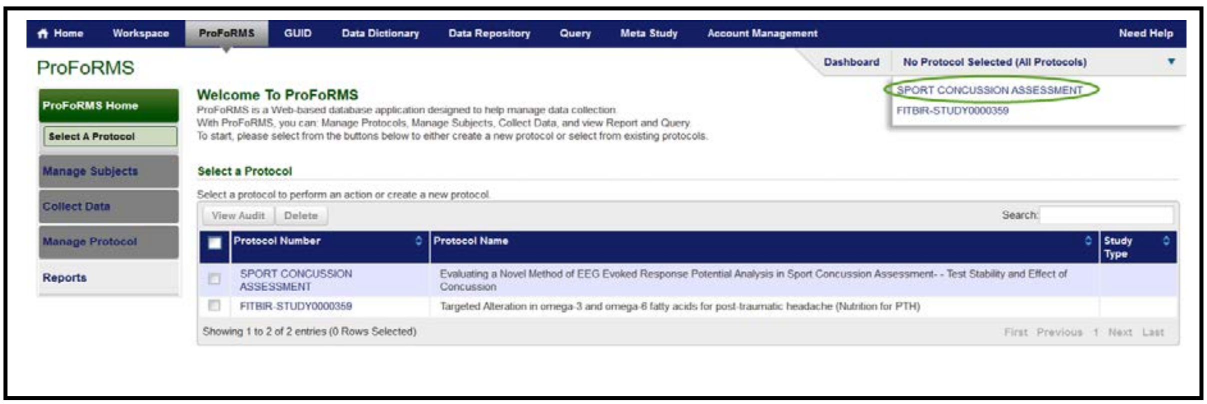
This report lists the GUIDs (including Pseudo-GUIDs) without collections.

To view GUIDS Without Collections Report: Perform the following actions:

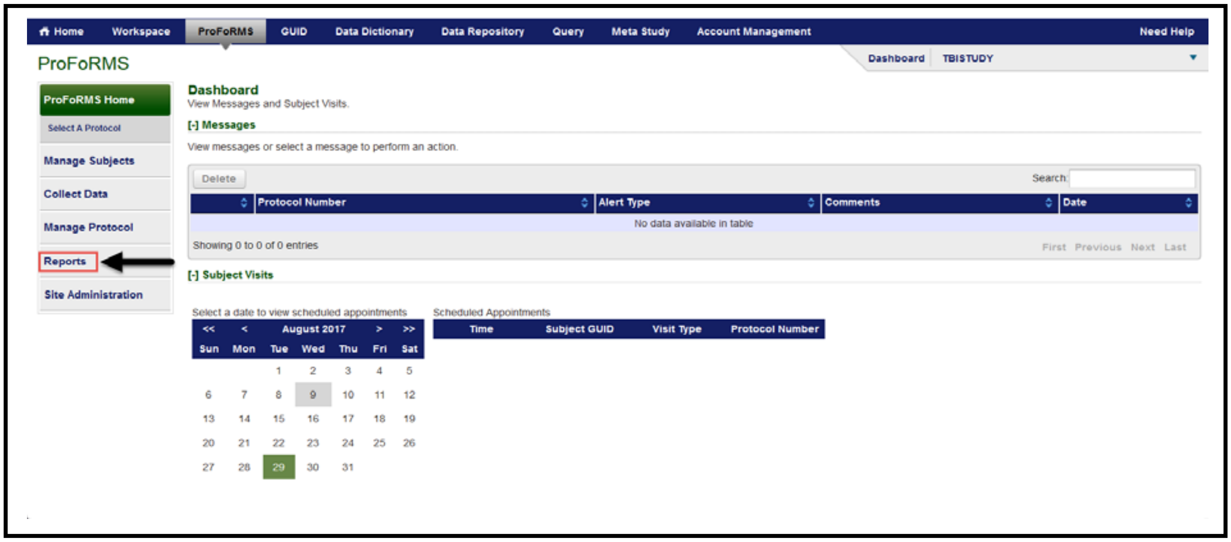
1. Navigate to the **ProFoRMS** module



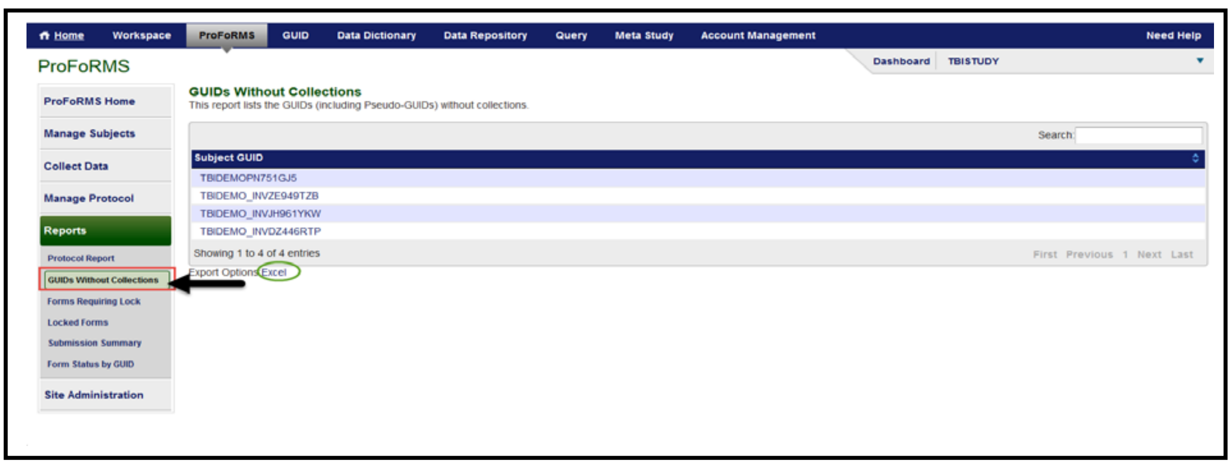
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



4. Click the **GUIDS Without Collections** on the left-side tool bar. The GUIDS Without Collections Report Information page appears. The report appears showing the Subject GUID. You may use the export feature to export the report to Excel format.

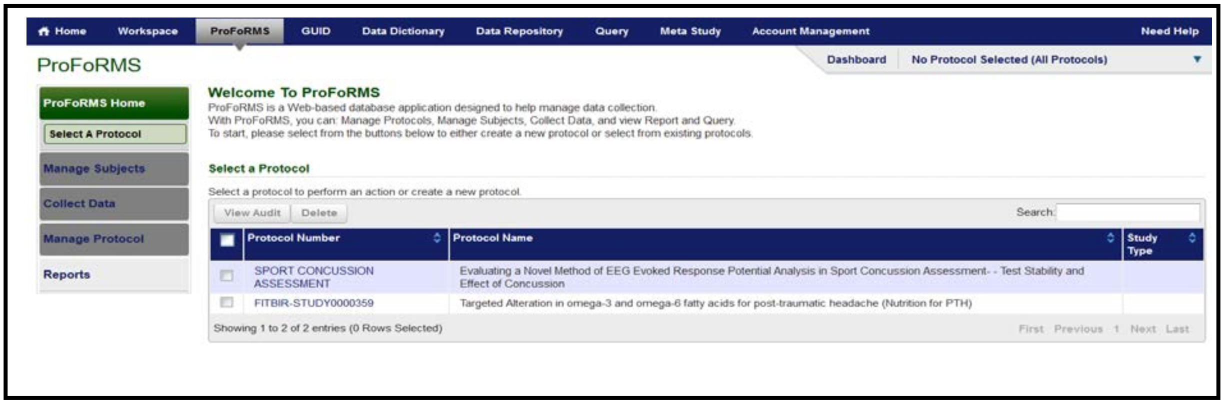


3.9.3 Forms Requiring Lock Report

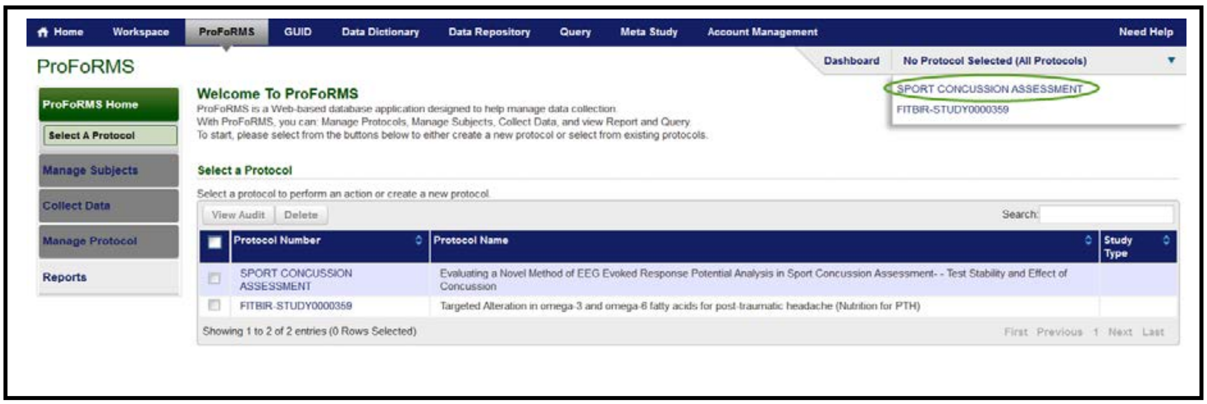
This report contains the list of collections that are in progress and it has been more than 30 days since creation.
In addition, this table also provides collections that have been completed, but not locked.

To view Forms Requiring Lock Report: Perform the following actions:

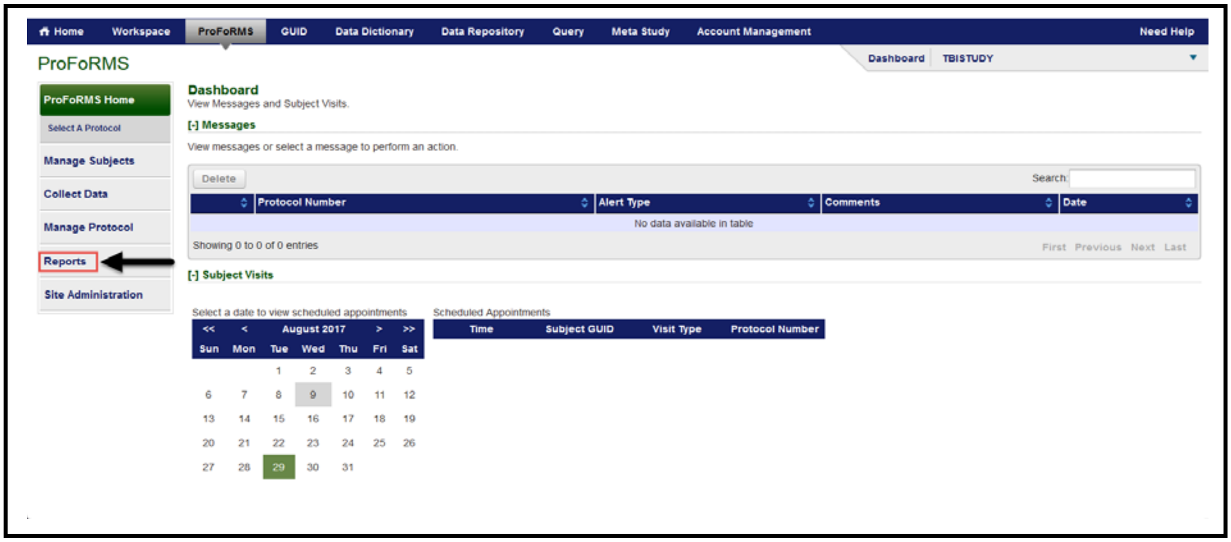
1. Navigate to the **ProFoRMS** module



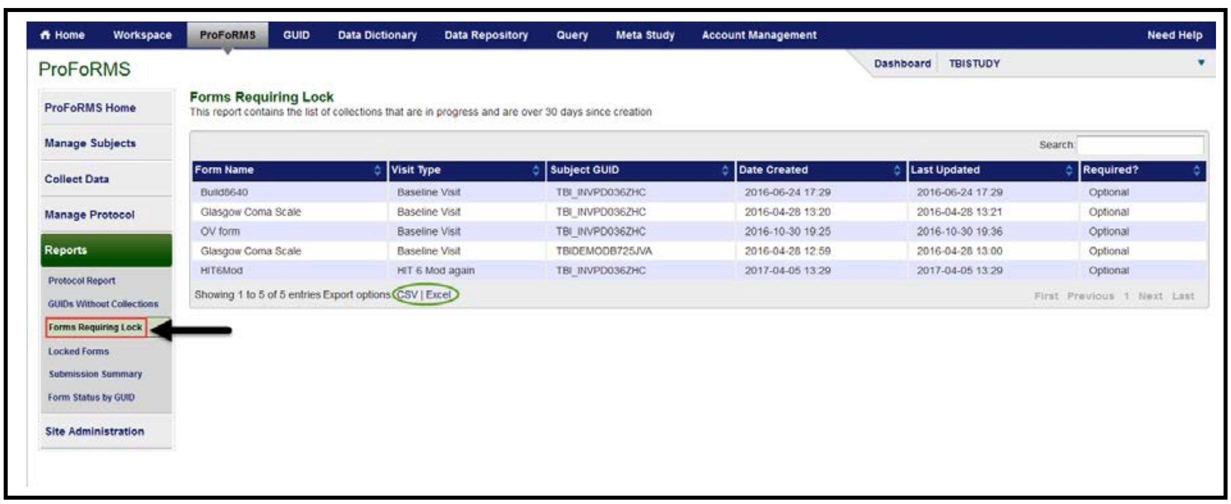
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



4. Click the **Forms Requiring Lock** on the left-side tool bar. The Forms Requiring Lock Report Information page appears. The report appears showing the **Form Name, Visit Type, Subject GUID ID, Date Created, Last Updated, Required**?. You may use the export feature to export the report to either CSV or Excel format.

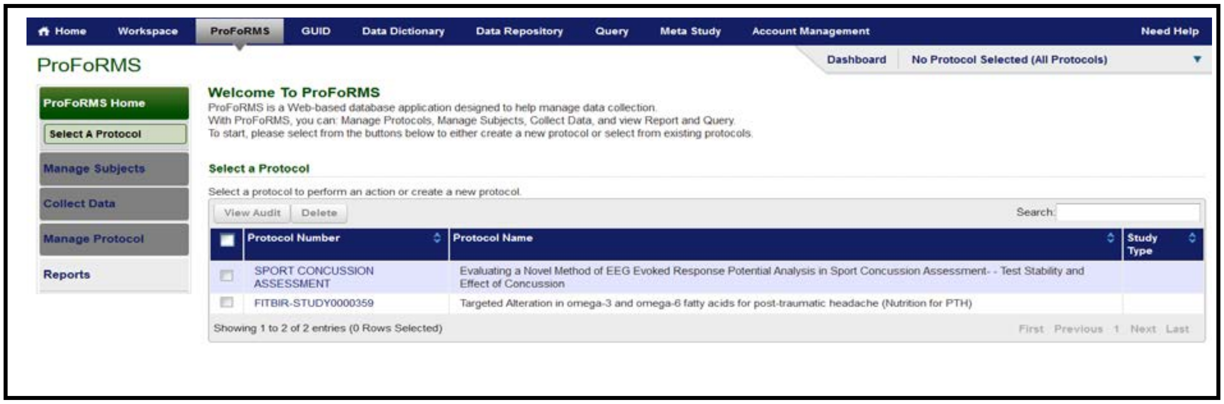


3.9.4 Submission Summary Reports

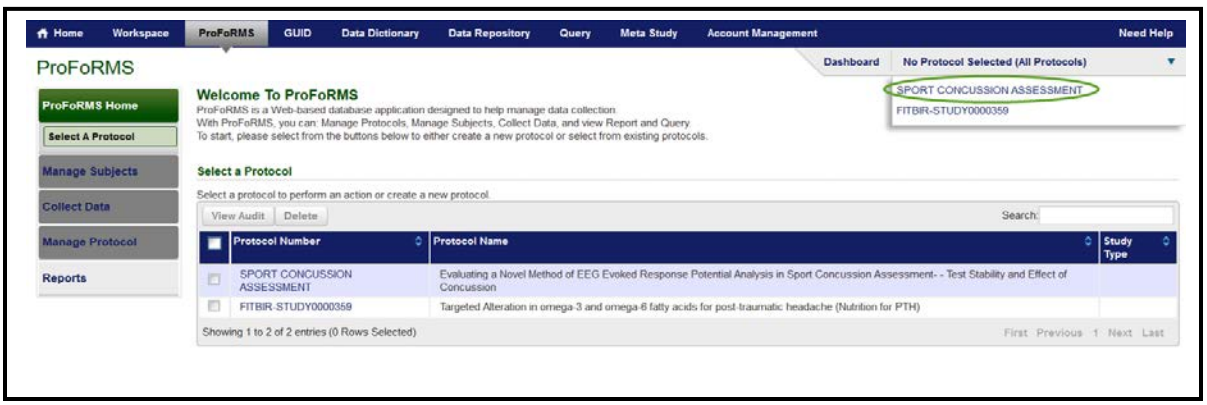
This report lists the status of collections submitted to the data repository for this protocol.

To view Submission Summary Report: Perform the following actions:

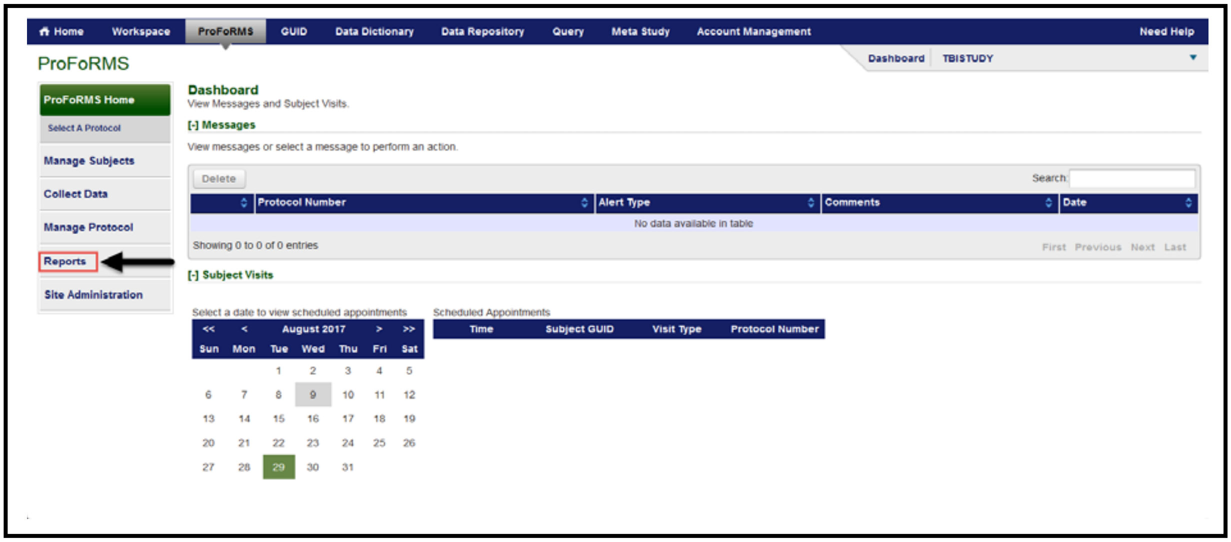
1. Navigate to the **ProFoRMS** module



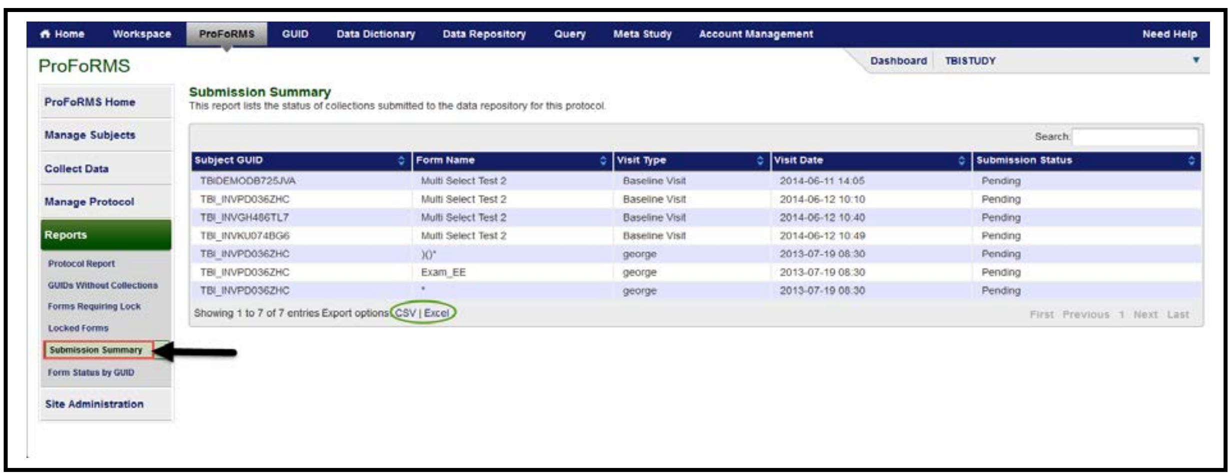
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



4. Click the **Submission Summary Report** on the left-side tool bar. The Submission Summary Report Information page appears. The report appears showing the Subject GUID Form Name, Visit Type, Visit Date, and Submission Status. You may use the export feature to export the report to either CSV or Excel format.

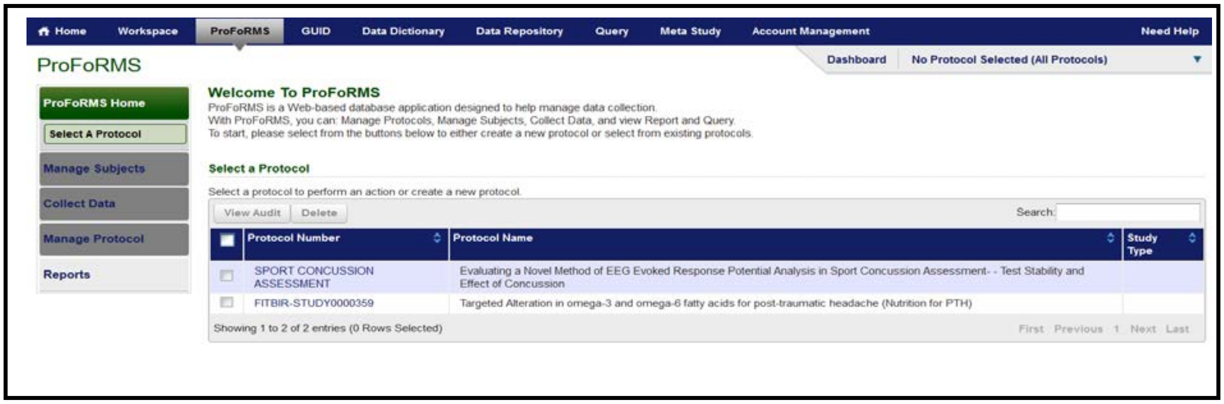


3.9.5 Form Status By GUID Report

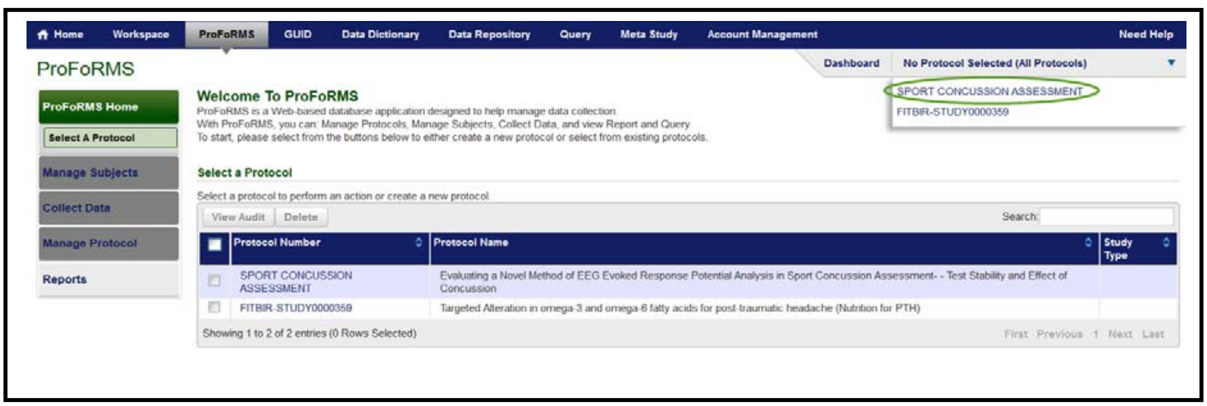
Forms Status by GUID report shows the completion status of forms by GUID for each visit type. To use this report please select a GUID from the drop-down or start typing to auto complete result.

To view Submission Summary Report: Perform the following actions:

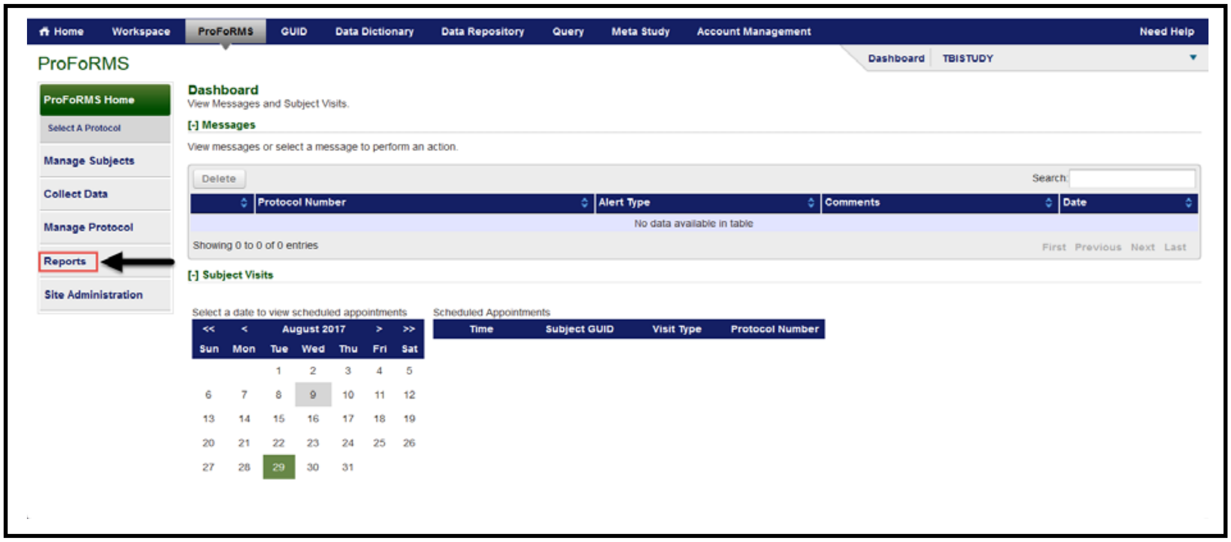
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.

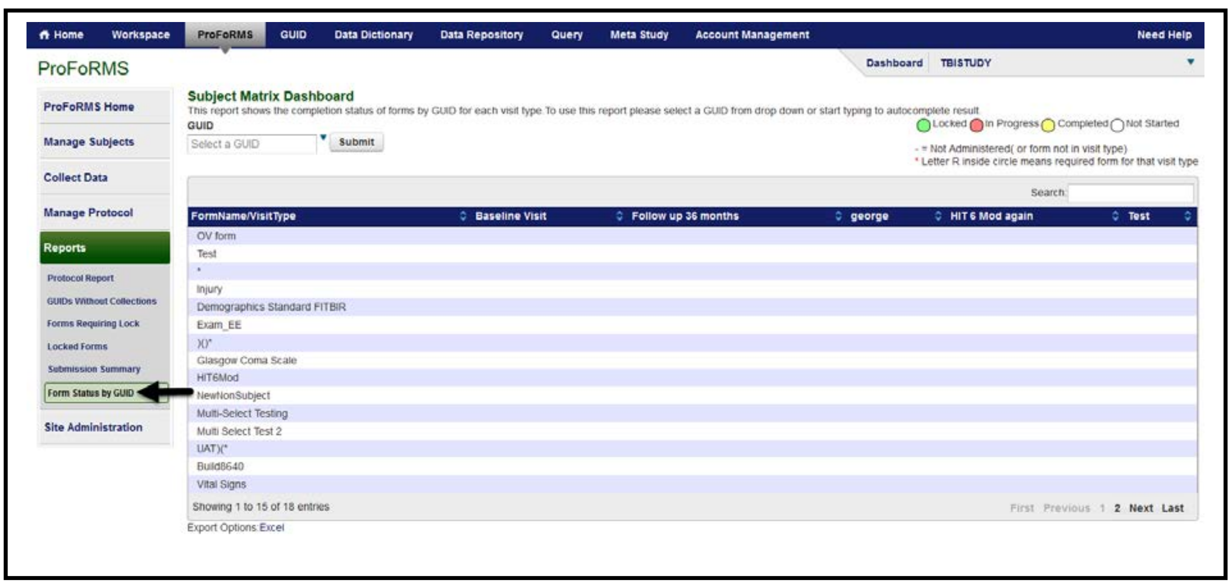


3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.

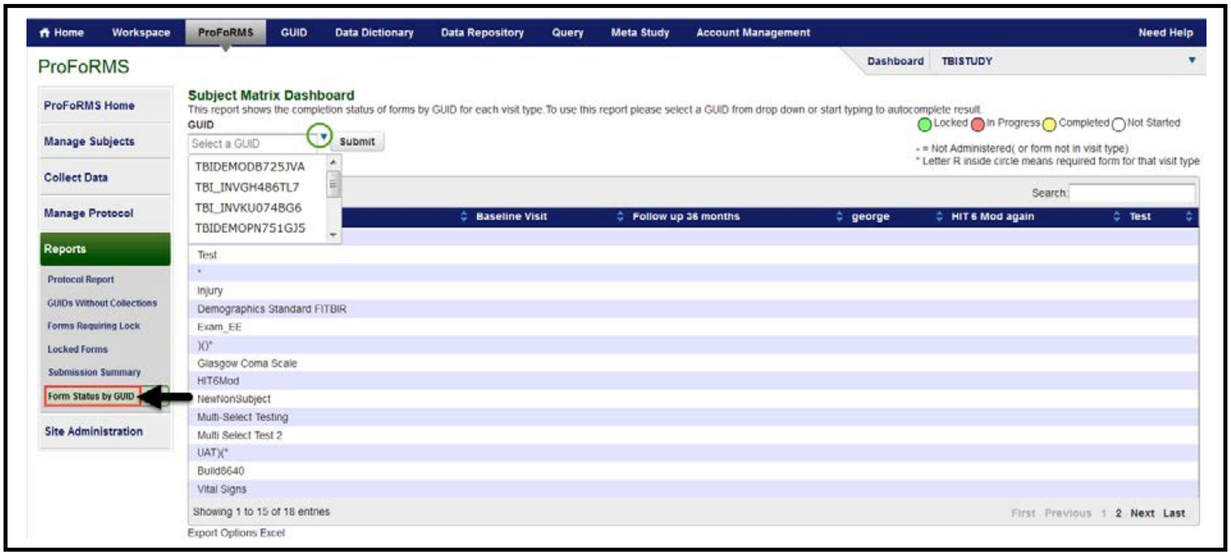


4. Click the **Form Status Submission by GUID** on the left-side tool bar. The report appears listing the competition status of forms by GUID for each visit type.

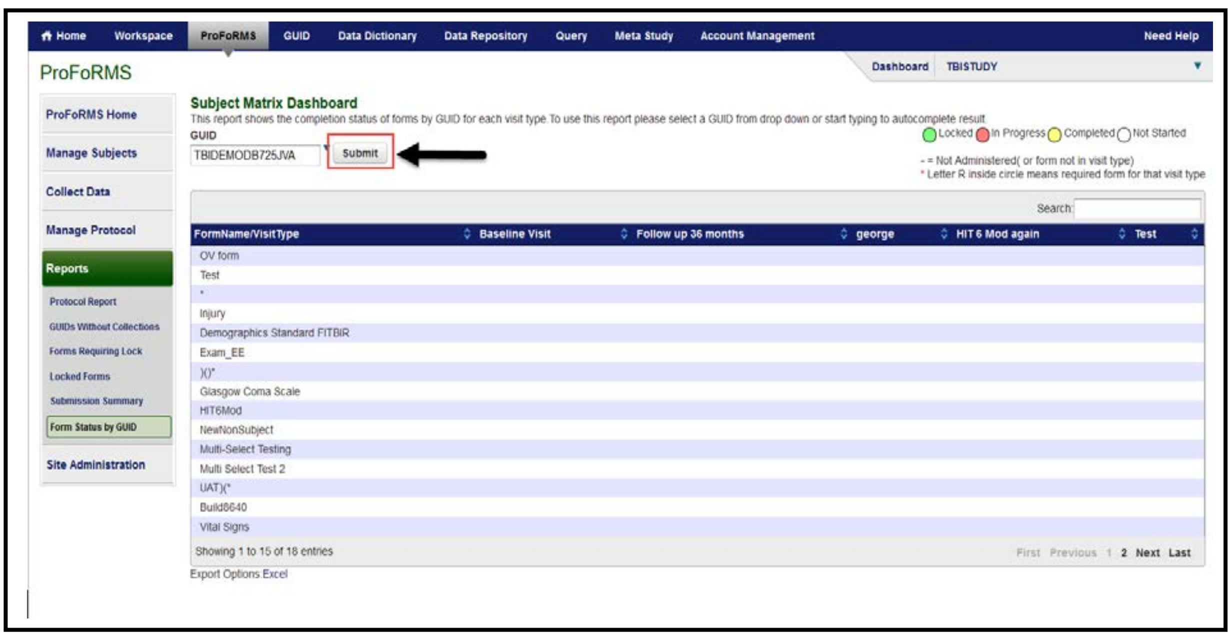
To use this report, you MUST select a GUID from the drop-down menu or start typing to autocomplete the result.



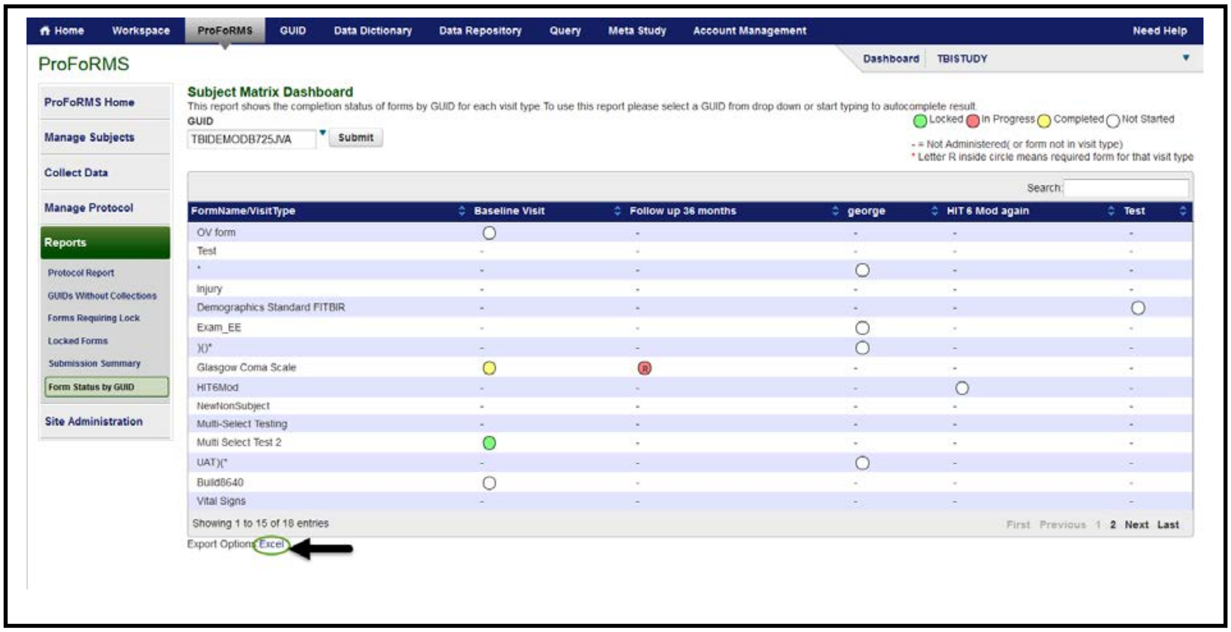
5. Select a GUID from the drop-down menu or start typing to auto-complete the result.



6. Click the **Submit** button.



7. Click the **Excel** option to export the report.



ICON KEY

Notes

Important Information

Things to Note:

Locked In Progress Completed Not Started

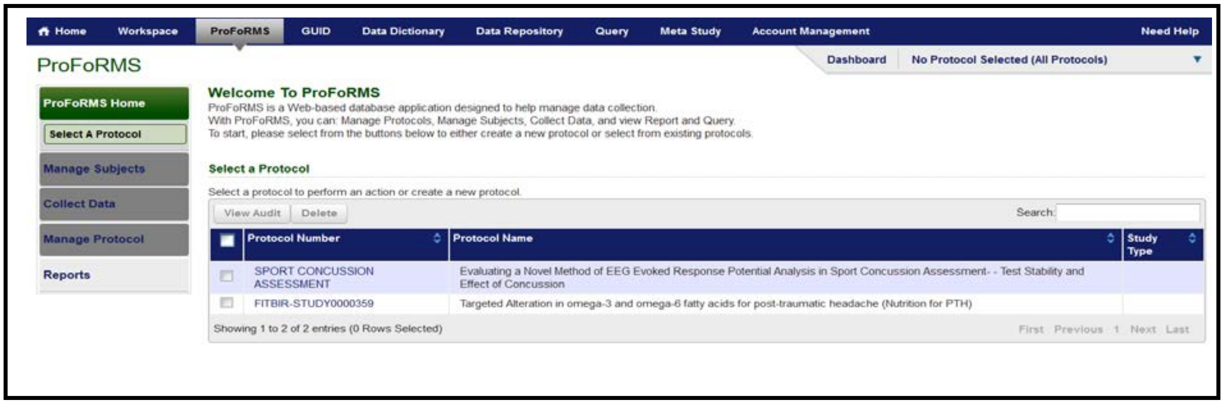
- = Not Administered(or form not in visit type)
* Letter R inside circle means required form for that visit type

3.9.6 Completed Visits Report

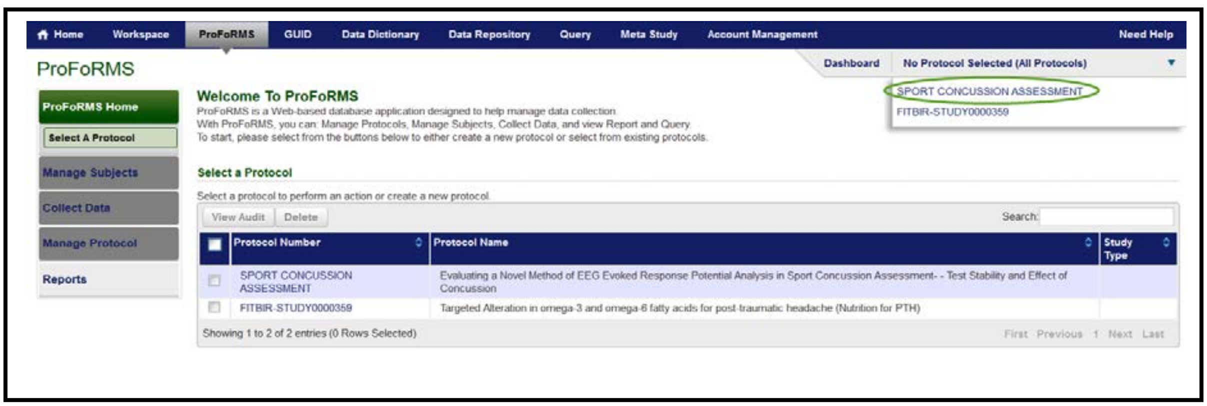
This report shows the total number of subjects within each protocol and the number of subjects that have completed all required forms within each visit type.

To view Completed Visits Report: Perform the following actions:

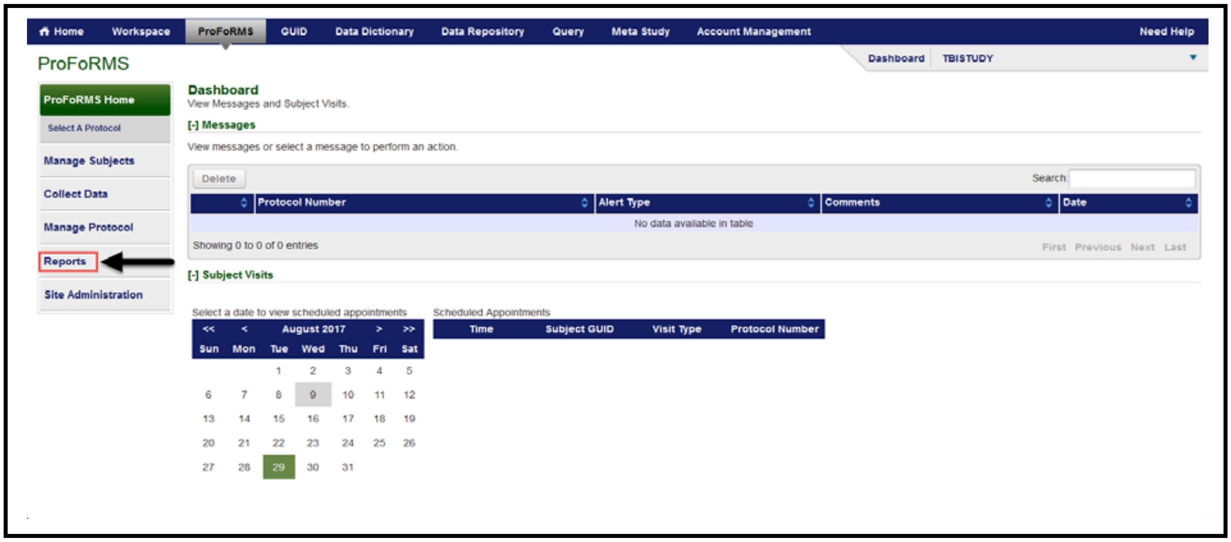
1. Navigate to the **ProFoRMS** module



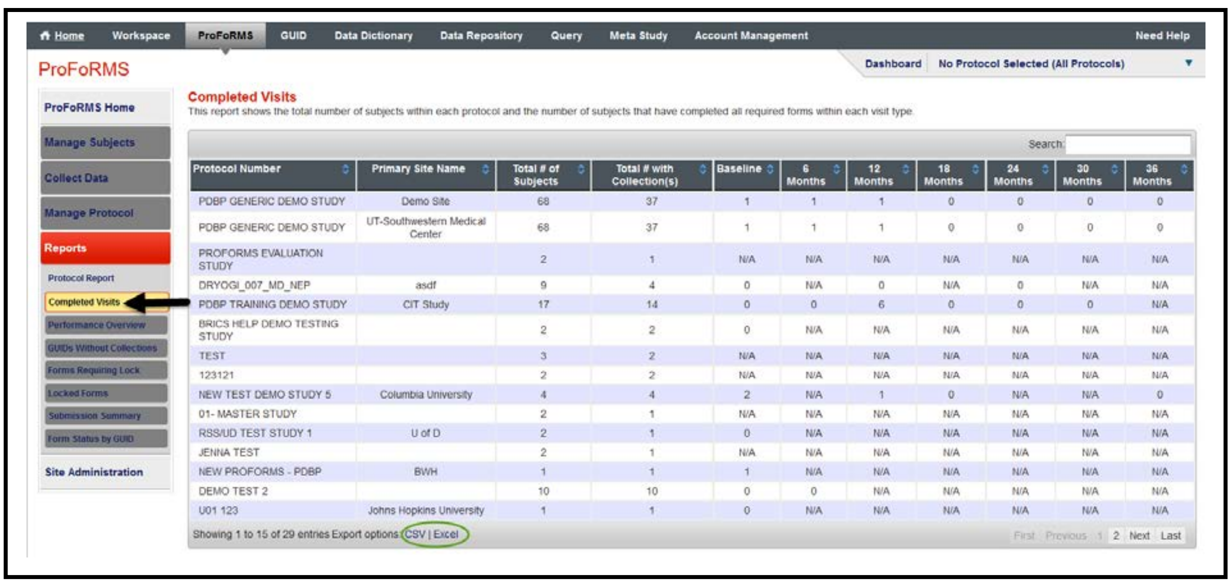
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



4. Click the **Completed Visits** on the left-side tool bar. The report appears listing the Protocol Number, Primary Site Name, Total Number of Subjects, Total Number with Collections, Baselines, 6 Month, 12 Months, 18 Months, 24 Months, 36 Months, 42 Months, 48 Months, 54 Months, 60 Months, 72 Months. **<u>Note</u>: This report is only available to the PDBP.** You may use the export feature to export the report to either CSV or Excel format. N/A signifies that no data has been collected for that visit type.

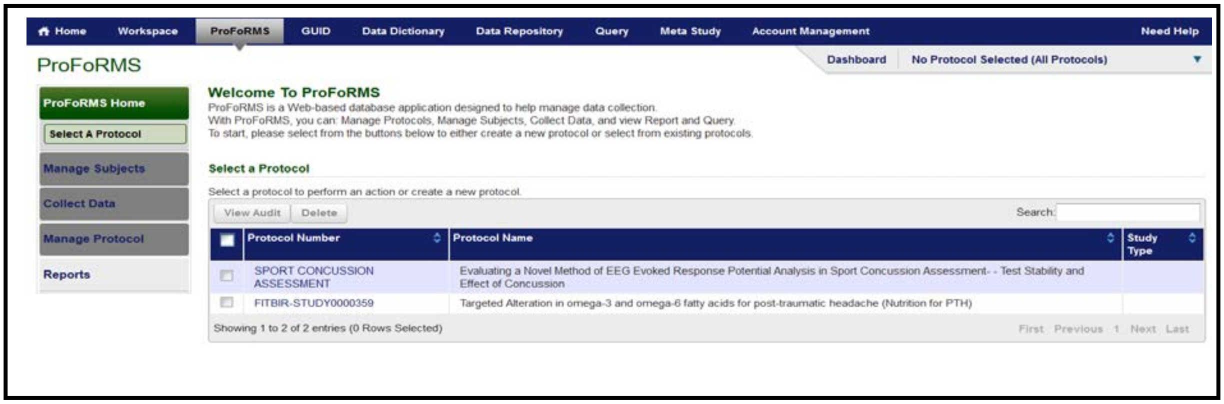


3.9.7 Performance Overview Report

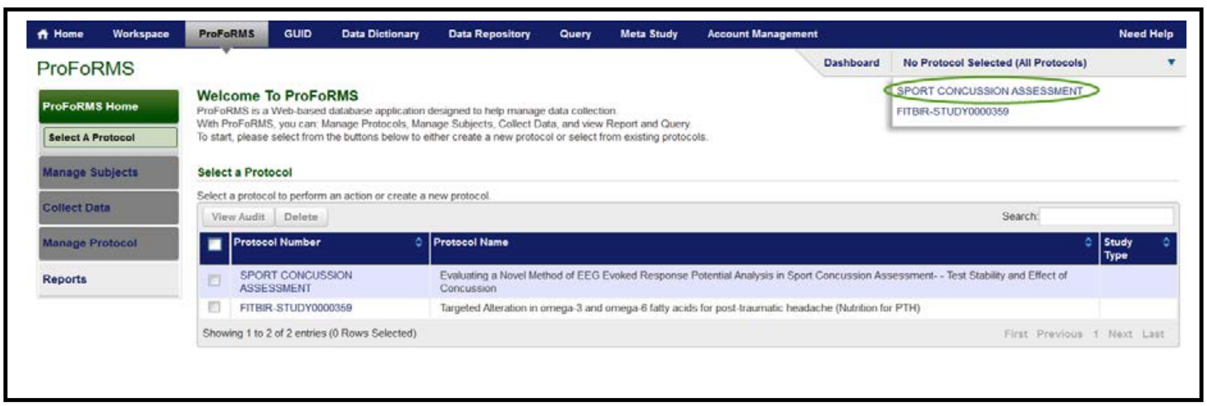
This report shows the total number of In Progress and Locked forms.

To view Performance Overview Report: Perform the following actions:

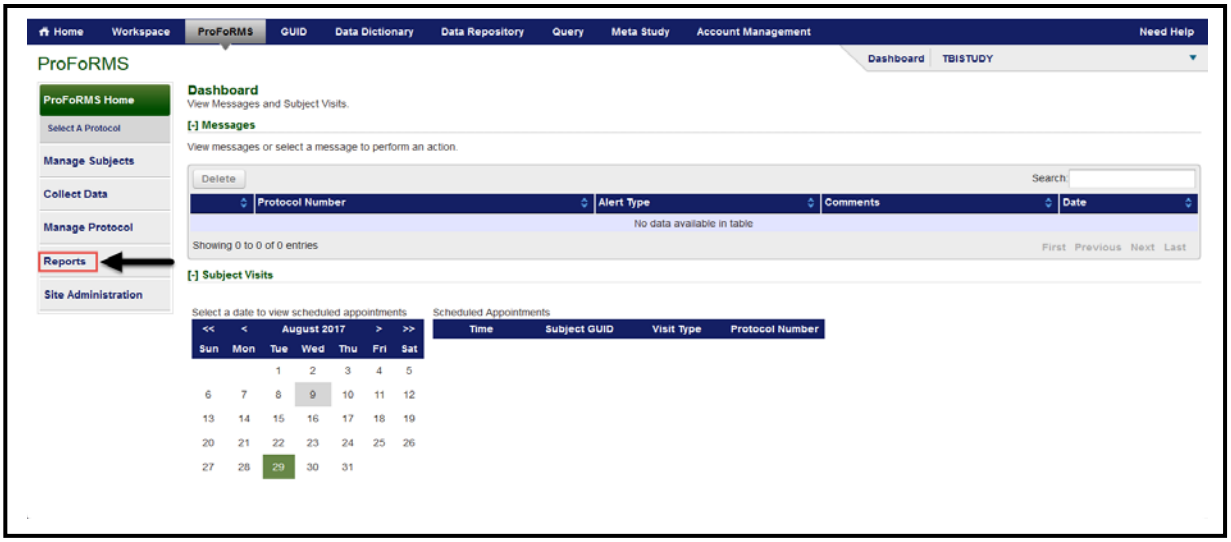
1. Navigate to the **ProFoRMS** module



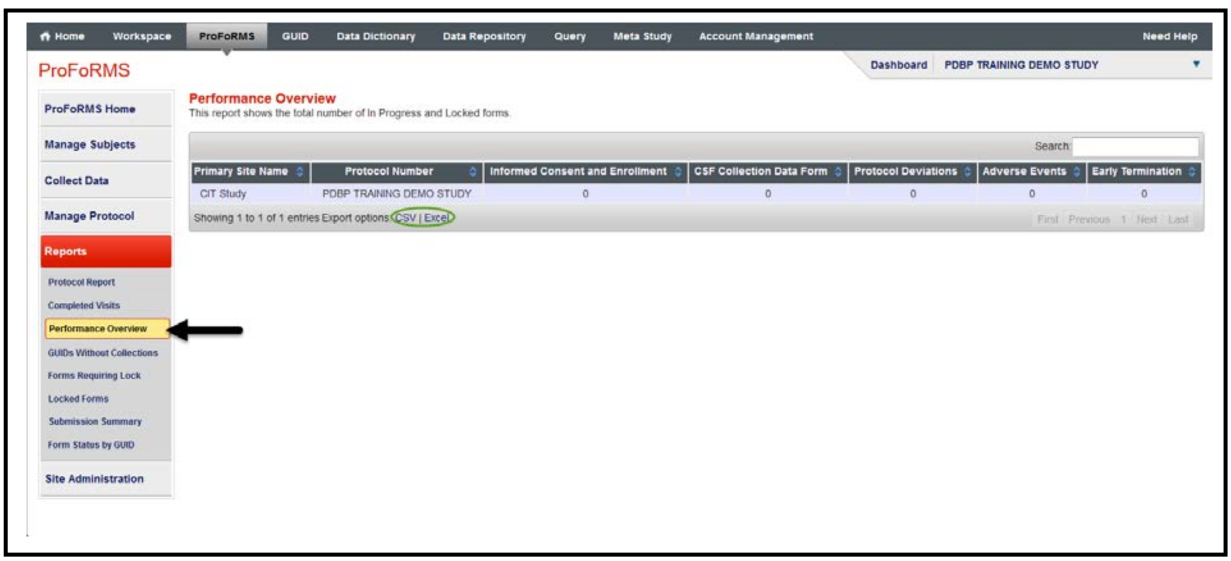
2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



4. Click the **Performance Overviews** on the left-side tool bar. The report appears listing the Primary Site Name, Protocol Number, Informed Consent and Enrollment, CSF Collectons, Protocol Deviations, Adverse Events, Early Termination, **Note: This report is only available to the PDBP.** You may use the export feature to export the report to either CSV or Excel format.

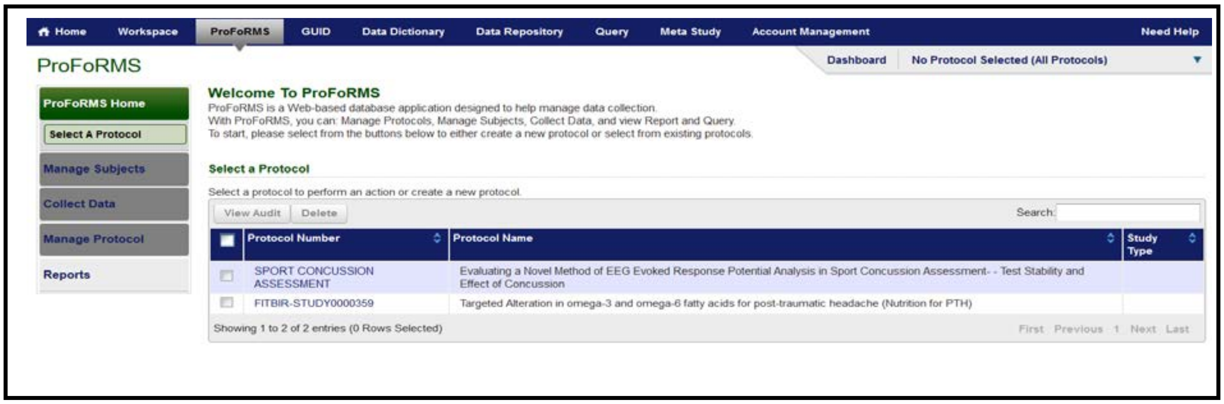


3.9.8 Locked Forms Report

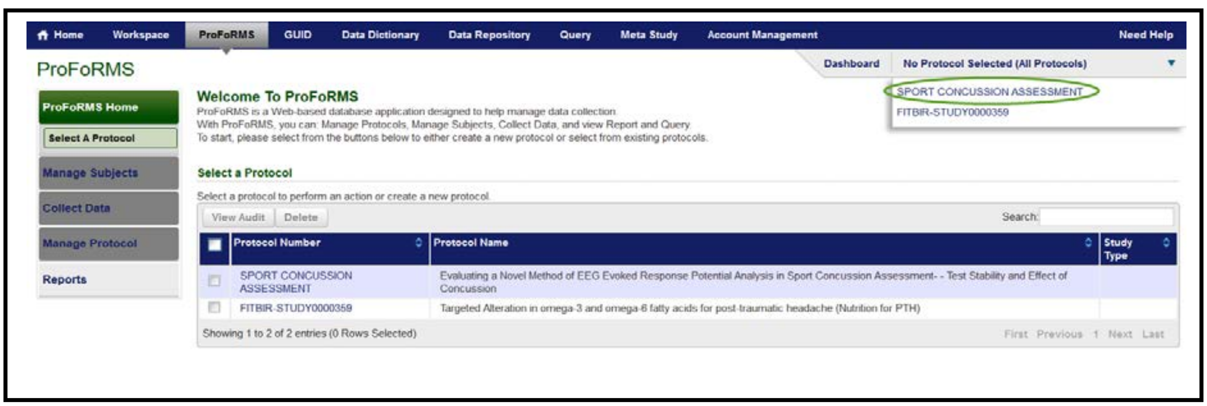
This report shows the forms that are completed in data collection, and it is filled out by subject.

To view Performance Overview Report: Perform the following actions:

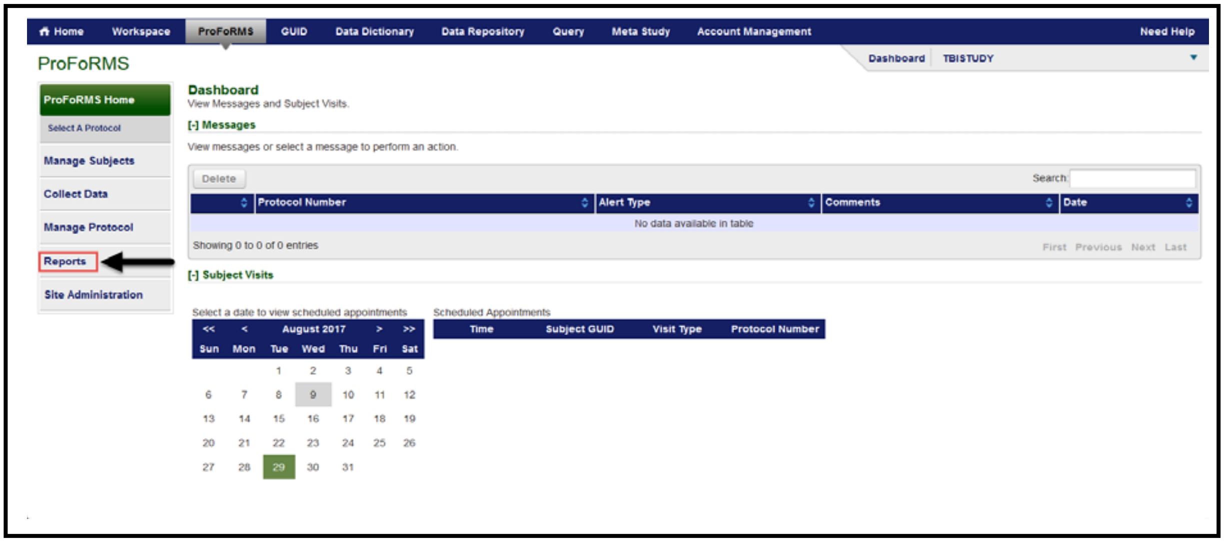
1. Navigate to the **ProFoRMS** module



2. Select a **Protocol** by using the drop-down menu located on the top right-hand.



3. The ProFoRMS Dashboard opens. Click **Reports** on the left-side tool bar.



4. Click the **Locked Forms** on the left-side tool bar. The report appears listing the Subject GUID, Filled Form, Visit Date, Number of Questions Answered and Visit Type. **<u>Note</u>: This report is only available to the PDBP.** You may use the export feature to export the report to either CSV or Excel format.